CODONICS®
We bring the future into focus

SLS 500i
Safe Label System™

User's Manual

Codonics® Catalog Number SLS500-MNLU
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Codonics, Inc.
17991 Englewood Drive
Middleburg Heights, OH 44130 USA
440.243.1198 Phone
440.243.1334 Fax
Email info@codonics.com
www.codonics.com

CAUTION Federal law restricts this device to be sold for use by or on the order of a physician.

European Authorized Representative:

EC REP

CEpartner4U
Esdoornlaan 13,
3951DB Maarn
The Netherlands
Tel.: +31 343 442 524

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Preface

Conventions Used in This Manual

Bulleted Lists

Bullets are used to display a list of nonprocedural items. For example:

The following events trigger a synchronization of the Safe Label System data to that stored on the SmartDrive:

- Automatically every 15 minutes
- Formulary updates

Numbered Steps

The  icon indicates the beginning of a procedure. The steps in a procedure are numbered. For example:

To install an ink cartridge

1. Open the front cover.
2. Press the Ink button.

Notes

Notes contain additional information related to a topic or procedure. For example:

NOTE: *The system will ensure that a test print is performed at least once a day.*

Cautions and Warnings

Cautions alert you to actions or situations that could cause harm to equipment or data. For example:

CAUTION Do not touch the copper area of the cartridge print head.

Warnings alert you to actions or situations that could result in personal injury. For example:

WARNING When the front cover is open, avoid contact with the label cutter.

Important Information and Filenames

Bold type is used for emphasis, user interface object names, and paths or filenames. For example:

- The **Barcode Scanner** scans drug container barcodes for identity and verification.
- Use the controls to correct the date and time, then press the **OK** button.

Purpose and Scope

Refer to this User's Manual for procedures on how to perform the SLS user operations, including:

- Setting up the hardware and software
- Performing basic functions such as logging in and out, and configuring some system settings (for example, sound volume, brightness)
- Printing and confirming syringe labels
- Checking drug syringes by scanning their barcodes
- Maintaining the system
- Monitoring system status and troubleshooting common problems

Product Information

For technical assistance with the SLS, call Codonics Technical Support at the following number:

Phone: **+1 440.243.1198**
Toll Free: **800.444.1198 (USA only)**

Technical Support is available 24/7/365. Technical Support is also available online via email and the Codonics web site:

Email: **support@codonics.com**
Web Sites: **www.codonics.com** and **www.safelabel.com**

General product information can also be requested by sending email to:

Email: **info@codonics.com**

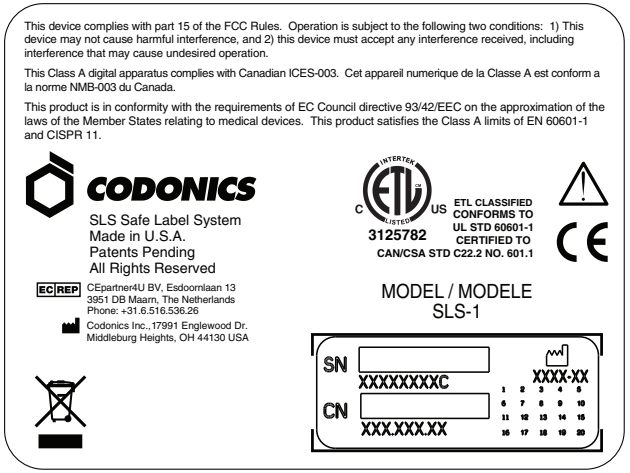
Please include your postal mailing address and telephone number in the email message. Basic product information is returned via email unless otherwise requested.

Warnings and Limitations of Use

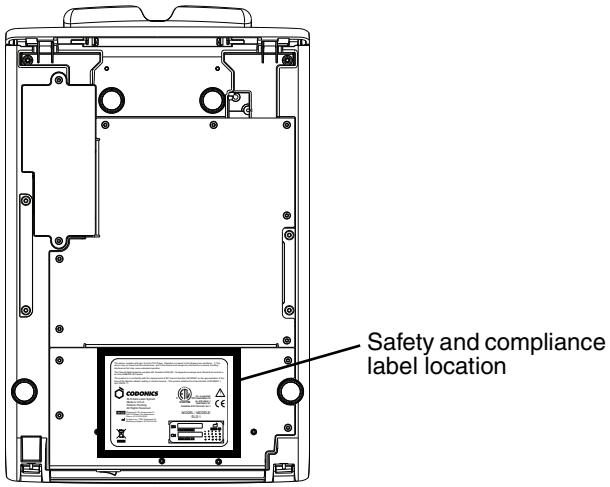
Location of Safety and Compliance Labels

Codonics is in compliance with various regulations, details of which are listed in Appendix B.

The SLS safety and compliance label, shown below, is located on the bottom of the device (shown on the following page).



SLS safety and compliance label



SLS safety and compliance label, on bottom of device

Voltage Warning

The exclamation point within a triangle is intended to alert the user to the presence of important operating and maintenance (servicing) instructions in the literature accompanying this device.

REFER SERVICING TO QUALIFIED SERVICE PERSONNEL. REMOVAL OF LABELS, COVERS, OR ENCASEMENT FASTENERS MAY VOID THE WARRANTY.

THIS APPARATUS MUST BE ELECTRICALLY GROUNDED.

TO PREVENT FIRE OR SHOCK HAZARD, DO NOT EXPOSE THIS DEVICE TO RAIN OR MOISTURE.

EQUIPMENT IS NOT TO BE USED AS A COMPONENT OF A LIFE SUPPORT SYSTEM. Life support devices or systems are devices or systems that support or sustain life, and whose failure to perform can be reasonably expected to result in a significant injury or death to a person. A critical component is any component of a life support device or system whose failure to perform can be reasonably expected to cause the failure of the life support device or system, or to affect its safety or effectiveness.

WARNING Grounding reliability can be achieved only when the SLS is connected to a receptacle marked "Hospital Only" (that is, "Hospital Grade").

WARNING The power cord connected to the SLS is the main disconnect for the system.

WARNING To disconnect overall power to the SLS prior to servicing it, power off the system (refer to "Powering Off the System" on page 3-20).

Dangers Électriques

Le point d'exclamation situé à l'intérieur d'un triangle représente un point d'instruction important dans l'utilisation ou l'entretien de cette appareil.

POUR SOUTIEN ADRESSEZ-VOUS AU PERSONNEL QUALIFIE. LE RETRAIT DE LES ETIQUETTES, LES COUVERTURES, OU LES ATTACHES PEUT ANNULENT LA GARANTIE.

CET APPAREIL DOIT ETRE ELECTRIQEMENT RELIE A LA TERRE.

N'EXPOSEZ PAS CET APPAREIL À LA PLUIE OU L'HUMIDITÉ, EN RAISON DU RISQUE DE FEU OU DE DÉCHARGES ÉLECTRIQUES.

Cet appareil ne doit pas être utilisé comme composant d'un système d'assistance vitale. Les devis ou les systèmes vitale sont quelque devis ou système qui assistent ou soutiennent la vie, et si les devis ou systèmes échouent, on peut attend raisonnablement la mort ou la blessure. Cet appareil ne doit pas être utilisé dans des conditions où la défaillance de l'appareil pourrait entrainer la blessure ou la mort de quelqu'un.

ATTENTION Une mise à la terre fiable est possible seulement pendant que le SLS est connecté aux appareils marqué "Hospital Only" (de qualité hositalière).

ATTENTION Le fil électrique connecté à le SLS sont le système de coupure principal de l'appareil.

ATTENTION Pour débrancher le fil électrique avant le soutien, se déconnecter et puis éteint le système (renvoyer à « Powering Off the System » sur la page 3-20).

Laser Warning

This device emits CDRH/IEC Class 2 laser and IEC Class 1M light. Do not stare into beam.

Danger du Faisceau Laser

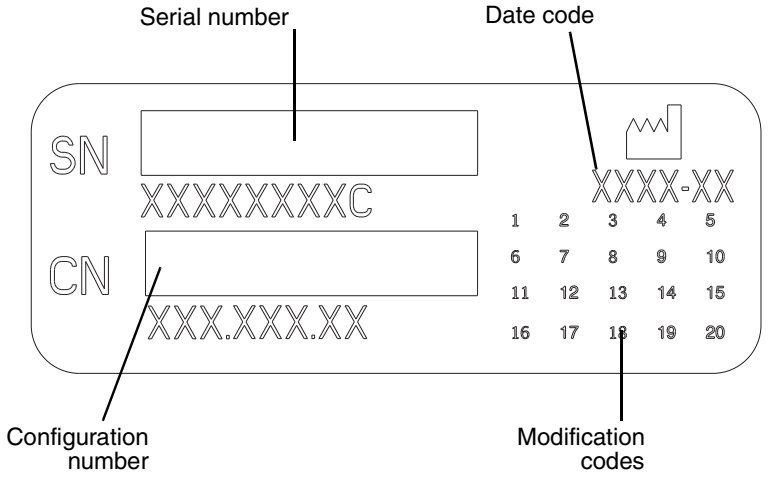
Ce devis émit CDRH/IEC Class 2 laser et IEC Class 1 M lumière. Ne regarde pas dans le rayon.

Serial Number, Configuration, Date Code, and Modification Codes

The serial number label is placed onto the safety and compliance label.

The serial number label includes the following information:

- The serial number (SN), which uniquely identifies the unit.
- The configuration number (CN), which details the build configuration.
- The modifications codes, which are to the right of the CN number and are a series of 20 numbers. When any of these numbers are blocked out, that identifies a modification that was made to the unit.
- The date code in YYYY-MM format below the factory date code symbol.



Serial number label

Potential for Radio Frequency Interference on Device Operation

Both portable and mobile RF communications equipment can affect medical electrical equipment, including the SLS. The SLS is intended for use in the electromagnetic environment specified in the guidance and manufacturer's declaration section.

Potential for Radio and Television Interference

The SLS generates and uses radio frequency energy, and if not installed and used properly, that is, in strict accordance with the manufacturer's instructions, may cause interference to radio and television reception. It has been type tested and found to comply with Class A emission limits for a computing device in accordance with the specifications in Subpart J of Part 15 of FCC Rules, which are designed to provide reasonable protection against such interference when operating in a commercial environment. The SLS is not intended for use in a residential Class A environment. The SLS requires a medical power/ground. If your SLS does cause interference to radio or television reception, you are encouraged to try to correct the interference by one or more of the following measures:

- Reorient the receiving antenna
- Relocate the SLS with respect to the receiver

If necessary, you should consult Codonics Technical Support or an experienced radio/television technician for additional suggestions. You may find the following booklet prepared by the Federal Communications Commission helpful: *How to Identify and Resolve Radio-TV Interference Problems*. This booklet is available from the U.S. Government Printing Office, Washington, D.C. 20402, Stock No. 004-000-00345-4.

Le présent appareil numérique n'émet pas de bruits radio-électriques dépassant les limites applicables aux appareils numériques de la Classe B prescrites dans le Réglement sur le brouillage radioélectrique édicté par le ministére des Communications du Canada.

This product is in conformity with the protection requirements of EC Council directive 89/336/EEC on the approximation of the laws of the Member States relating to electromagnetic compatibility. This product satisfies the Class A limits of EN 55011. A declaration of conformity with the requirements of the Directive has been signed by a Codonics vice president.

Guidance and Manufacturer's Declaration—Electromagnetic Emissions

The SLS is intended for use in the electromagnetic environment specified below. The customer or the user of the SLS should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment—Guidance
RF emissions CISPR 11	Group 1	The SLS uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The SLS is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emission IEC 61000-3-2	Class A	
Voltage fluctuations/Flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration—Electromagnetic Immunity

The SLS is intended for use in the electromagnetic environment specified below. The customer or the user of the SLS should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Main power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV lines(s) to earth	± 1 kV line(s) to line(s) ± 2 kV lines(s) to earth	Main power quality should be that of a typical commercial or hospital environment.
Voltage dips, shot interruptions, and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T <95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	<5% U_T (<95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	Main power quality should be that of a typical commercial or hospital environment. If the user of the SLS requires continued operation during main power interruptions, it is recommended that the SLS be powered from an uninterruptible power supply or a battery.
Power frequency (50/65 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: U_T is the AC main voltage prior to application of the test level.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the SLS, including cables, than the recommended separation distance calculated from the equation applicable to the frequency to the transmitter. **Recommended separation distance:** $d = 1.17\sqrt{P}$
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	$d = 1.17\sqrt{P}$ 80 MHz to 800 MHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 2.33\sqrt{P}$ 800 MHz to 2.5 GHz
			where *P* is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TB broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength is the location in which the SLS that is used exceeds the applicable RF compliance level above, the SLS should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the SLS.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Safety Precautions

- Never connect the device's external power supply to any outlet or power supply that has a voltage or frequency different than that specified (100 – 240 VAC, 50/60 Hz).
- Use only the external power supply provided with the device (Codonics part number SLS-PS).
- When replacing the device, always power it down (refer to "Powering Off the System" on page 3-20) and disconnect the AC power cord prior to servicing it.
- Damage to a power cord is a fire and shock hazard. When unplugging a power cord, hold it by the plug only and remove the plug carefully.
- If a power cord or external power supply needs to be replaced, replace it only with another Codonics power cord or Codonics external power supply. Alternatively, replace it with a power cord or external power supply manufactured specifically for your power configuration.
- If the device is smoking or making unusual sounds, power off and unplug the device immediately.
- Do not insert foreign objects of any kind into the device; doing so can constitute a safety hazard and cause extensive damage.
- Do not place any liquid containers on the device. If, for some reason, liquid seeps into the device, power off the device and unplug the power cord from the source outlet. If used without taking corrective measures, the device may be damaged.
- Do not expose the device to flammable gases in concentrations high enough to cause fire or explosion.

Précaution d'Emploi

- *Ne jamais brancher cet appareil sur une source d'alimentation électrique dont la tension ou la fréquence diffèrent des valeurs indiquées (100 – 240 VAC, 50/60 Hz).*
- *Utiliser uniquement l'alimentation électrique fourni avec l'appareil (numero de piéce Codonics SLS-PS).*
- *Avant de remplacer le appareil, veuillez à toujours éteindre l'appareil et n'oubliez pas de débrancher le câble secteur.*
- *Un fil électrique endommagé est une cause d'incendie ou de décharge électrique. En déconnectant le fil électrique, tenez-le seulement par la prise et retirez la prise soigneusement.*
- *Si le fil électrique ou l'alimentation électrique doit être remplacé, utilisez un fil électrique ou un alimentation électrique Codonics fabriqué spécifiquement pour votre appareil.*
- *Si l'appareil fume ou émet des bruits inhabituels arrêtez-le immédiatement et débranchez le fil électrique.*
- *N'introduisez aucun objet étranger dans l'appareil, cela peut être une source de danger et peut causer de graves dommages.*
- *Ne déposez aucun récipient à coté de l'appareil. Si pour quelque raison un liquide filtre à l'intérieur, arrêtez immédiatement l'appareil et débranchez le fil électrique. Toute nouvelle utilisation de l'appareil sans intervention peut causer de graves dommages.*
- *Ne pas utiliser l'appareil à coté d'une source de gaz inflammable.*

Location Precautions

- The operating ambient temperature range of the SLS is 15–30°C (59–86°F), with a relative humidity of 20%–80%.
- If the SLS is moved quickly from an extremely cold location to a warmer one, condensation is likely to form. Do not use the SLS if condensation has formed. Wait until the condensation has evaporated. You can speed up the evaporation time by moving the SLS to a dryer location.
- Do not place the SLS in a location with high humidity or high dust. Airborne dirt particles can cause print quality problems. Avoid placing the SLS in locations where ventilation ducts, open doors, or frequent passers-by might expose the SLS and labels to high levels of debris.
- Do not locate the SLS in hot-springs areas where hydrogen sulfide and acidic ions are likely to be generated.
- Do not locate the SLS where there are oily fumes and vapors.
- Do not locate the SLS in direct sunlight.
- Do not locate the SLS near sources of high RF energy.
- Do not locate the SLS where it might be subject to jarring or vibrations, such as a table or desk in a high-traffic area. Jarring and vibrations can affect the print quality of labels.
- If using a VESA mount to mount the device on a wall, stand, or anesthesia supply cart, refer to the VESA Mounting Interface Standard (MIS), available at **www.vesa.org**, for proper location and installation information.

Environnement de Fonctionnement

- *Les conditions normales d'utilisation de l'appareil sont : une température de 15 à 30°C et une humidité relative de 20 % à 80 %.*
- *En cas de variation rapide de la température, de la condensation peut se former. En ce cas la n'utilisez pas l'appareil, attendez que la condensation se soit évaporée. Vous pouvez accélère cette évaporation en déplacent l'appareil dans un endroit sec.*
- *Toujours placez l'appareil dans une zone propre et non-humide. Des particules de poussières peuvent causer des disfonctionnements de la qualité d'imprimante. Évitez de placer l'appareil à proximité d'une bouche de ventilation, d'une porte, ou d'un endroit très fréquenté car cela pourrait exposer l'appareil ainsi que les étiquettes à la poussière.*
- *Ne placez pas l'appareil à proximité d'une source de chaleur ou de substances acides.*
- *Ne placez pas l'appareil dans une endroit où il y a des vapeurs huileuses et grasses.*
- *N'exposez pas l'appareil à la lumière directe du soleil.*
- *Ne placez pas l'appareil près d'une source haute fréquence.*
- *Ne placez pas l'appareil dans un lieu où il pourrait être exposé à des vibrations, car cela peut nuire l'impression des média.*
- *Si vous utilisez un bras de montage VESA pour monter l'appareil sur un mur, une potence ou un charriot d'anesthésie, veuillez vous réferrer aux instructions de montage VESA (MIS) sur* ***www.vesa.org*** *pour de plus amples informations.*

Cleaning Precautions

To avoid damage to the device, observe the following general precautions for cleaning the device:

- Apply the cleaner to a clean, lint-free cloth first and then clean the device. Liquid applied directly to the device could possibly leak inside the device and cause damage. Use extra caution when cleaning around the vents on the back of the touch screen and speaker.
- Allow the device to completely dry before operating it again.
- Many plastic components are used in the SLS construction. Coat flecking and deformation is likely to occur if the device is wiped with chemical dusters, benzene, thinners, insecticides, or other solvents. Rubber and PVC materials left in contact with the SLS for extended periods of time will cause damage. Never use petroleum-based solutions or abrasive cleansers.
- Never use abrasive material.
- Always dilute cleaning agents according to the manufacturer's instructions, or use the lowest possible concentration.
- Do not allow the cleaning agent to remain on the device surfaces. Wipe it off immediately with a lint-free cloth moistened with water.

For cleaning instructions, refer to "Cleaning the Enclosure" on page 5-2.

Précautions d'Entretien

- *Pour évité les dommages à appareil, regardez les précautions d'entretien:*
- *Appliquez le nettoyeur sur un tissu propre et puis nettoyez l'appareil. Liquide qui est applique directement sur le appareil peut causer les dommages. Utilisez beaucoup de précautions sur le conduit d'aération en bas de la écran et l'haut-parleur.*
- *L'appareil doit sécher complètement avant marcher encore.*
- *Il y a beaucoup des choses plastiques utilisant avec la fabrication du SLS. L'emploi des chiffons chimiques, de benzène, des diluants, des insecticides, ou des autres solvants peuvent causer les dommages à l'extérieur ou les déformations. Le caoutchouc ou le PVC qui ont beaucoup de contact avec le SLS causeront les dommages. N'utilisez jamais les nettoyeuses avec pétrole ou les nettoyeuses abrasives.*
- *N'utilisez jamais les matérielles abrasive.*
- *Toujours dilatez les nettoyeuses par les instructions du fabricant ou utilisez la concentration le plus faible.*
- *Ne laissez pas les nettoyeuses à la surface de l'appareil pour longtemps. Donnez un coup d'éponge propre.*

Pour instructions d'entretien, regardez « Cleaning the Enclosure » sur la page 5-2.

Disinfecting Precautions

To avoid damage to the device, observe the following general precautions for disinfecting the device:

- Do not use Povodine, Sagrotan, or Mucocit disinfecting agents or strong solvents (for example, acetone).
- Do not use any disinfecting agents that corrode or damage polycarbonate.

Précautions de Désinfection

- *Pour évité les dommages à appareil, regardez les précautions de désinfection.*
- *N'utilisez pas de Provodine, du Sagrotan, ou de Mucocit désinfectant ou les solvents fortes*
- *N'utilisez pas les désinfectants qui corroder polycarbonate.*

Media Precautions

- Unwanted labels should be destroyed or disposed of to ensure that improper labels are not used.
- Only use Codonics ink cartridges and labels to ensure proper operation of the device and proper labeling of syringes. Using unapproved ink cartridges and labels could lead to unacceptable results, including poor print quality and poor label adhesion to syringes.
- Never refill ink cartridges, as this can result in incorrect color usage.

Précautions de Média et Consommables

- *Les étiquettes inutilisées doivent être disposé ou détruit donc les étiquettes mauvais ne sont pas utiliser.*
- *Utilisez seulement les cartouches et étiquettes Codonics pour faire certain que le SLS fonctionner comme il faut.*
- *Ne rechargez jamais les cartouches. Ça peut avoir pour résulte les couleurs incorrects.*

Disposal Requirements

Disposal of this product and consumables shall be in accordance with all applicable laws and regulations in effect at the locality at the time of disposal. For additional information, refer to Appendix A, Hazardous Material Information.

Conditions et Règles d'Utilisation

L'utilisation de ce produit doit être conforme à toutes les lois et règlements applicables sur le lieu d'utilisation.

European Disposal Requirements

Codonics imagers and electronic accessory devices are not to be discarded or recycled; rather they are to be returned to the manufacturer. Contact Codonics directly or by the link provided for the latest information concerning:

- Identification of the country-specific Importer/Distributor/Producer
- Product return and treatment of our electronic products

Manufacturer: Codonics Inc.
17991 Englewood Drive
Middleburg Heights, OH 44130 USA
Phone: +1 440.243.1198
Fax: +1 440.243.1334
E-mail: WEEE@codonics.com
www.codonics.com and www.safelabel.com

Codonics electronic products and accessories bearing the following symbol are subject to European Directive on Waste Electrical and Electronic Equipment (WEEE) 2002/96/EC, amended by Directive 2003/108/EC. The EN 50419 symbol indicates separate collection and return required.

EN 50419 symbol

Indications for Use

Device Description

Drug preparation and administration in the perioperative environment are integral aspects of anesthesiologist's patient care responsibilities. The Codonics Safe Label System (SLS) is a simple, integrated system utilizing a barcode scanner to read and confirm drug identity from FDA NDC (National Drug Code) and other drug ID Barcodes from drug containers and automatically print labels for prepared drugs and other items in use on patients during surgical procedures. The labels are compliant with national regulations focused on improving medication safety in the perioperative environment.

The software components provide functions for scanning container barcodes; creating, reviewing, and approving the hospital-managed promotion of a formulary database; displaying on-screen and audibly confirming drug type; and printing ISO, ASTM, and TJC (The Joint Commission) content- and color-compliant labels with 2D barcodes. The system reads drug container barcodes and produces water resistant, color labels. The system can be integrated to function with an Anesthesia Information Management System (AIMS) workflow to provide real-time documentation of drug administration when the syringe 2D barcode is read.

Device Characteristics

The use of drug class specific pattern and color per ASTM D4774 and ISO 28625 Specifications for User Applied Drug Labels in Anesthesiology is configurable by site and dataset. *Formularies* (datasets) are uniquely named configurations that may differ in drugs, colors, dilutions, and comments to accommodate different practices within a single site or hospital (for example, pediatric versus cardiac).

Additional uses include producing labels for IVs and other artifacts used during a surgical procedure.

The Codonics SLS is generally placed in, however not limited to, the perioperative environment to identify syringes prepared for anesthesiology use during surgery.

Typical users of this system are trained professionals, including but not limited to physicians, nurses, and technicians.

The major characteristics and functions of the family of devices include:

- Scanning the drug container barcode directly from a vial or other type of container
- Decoding the manufacturer-issued barcode into the required FDA National Drug Code (NDC) or Unique Drug Identifier (UDI) number
- Referring the NDC/UDI number to a site-managed formulary lookup database
- Providing audio and ISO-compliant visual “readback” of the drug name
- Providing an alert if the drug container is listed as “recalled/obsolete” in the site’s formulary
- Printing an easy-to-read, water resistant ISO 26825 compliant color label meeting The Joint Commission medication management standards and the American Society of Anesthesiologists guidelines for labeling
- Providing the basic information by which the printed label barcode can be read to document medication administration in an AIMS
- Printing labels with insertion and expiration date and time for IV lines

Device Indications for Use Statement: Prescription Use Device

The Codonics SLS device and SLS software provides a simple computer-based barcode scanning and printing system to automatically verify drug identity from NDC and other drug container UDI barcodes, and to print labels for prepared drugs and other items in use on patients during surgical procedures.

The Codonics SLS is generally placed in, however not limited to, the perioperative environment to identify syringes prepared for anesthesiology use during surgery. Additional uses include producing labels for IVs and other artifacts used during a surgical procedure. SLS can also be used to print “non-surgical environment” color and text labels as required. Typical users of this system are trained professionals, including but not limited to physicians, nurses, and technicians.

1 Introduction

Welcome and Congratulations

Congratulations on your purchase of the Codonics® Safe Label System™ (SLS) medication labeling system!

We are pleased that you chose the SLS. We are confident that it will provide safe, compliant, fast medication labeling.

Product Features

Drug preparation and administration in the perioperative environment are integral aspects of anesthesiologist's patient care responsibilities. The SLS is a simple, integrated system utilizing a barcode scanner to read and confirm drug identity from FDA NDC (National Drug Code) and other drug ID barcodes from drug containers and automatically print labels for prepared drugs and other items in use on patients during surgical procedures. The labels are compliant with national regulations focused on improving medication safety in the perioperative environment.

The software components provide functions for scanning container barcodes; creating, reviewing, and approving the hospital-managed promotion of a formulary database; displaying on-screen and audibly confirming drug type; and printing ISO, ASTM, and TJC (The Joint Commission) content- and color-compliant labels with 2D barcodes. The system reads drug container barcodes and produces water resistant, color labels. The system can be integrated to function with an Anesthesia Information Management System (AIMS) workflow to provide real-time documentation of drug administration when the syringe 2D barcode is read.

Hardware Features

- **Integrated printer** produces syringe labels that include medication name and concentration; dilutions and diluents; preparation time and date; preparer; and expiration time and date.
- **Embedded computer** including USB and an integrated speaker.
- **Touch screen display** with an intuitive, easy-to-use interface. System operation and status information is easily accessible from the touch screen interface.

- **Barcode scanner** identifies medications.
- **High-quality Codonics SLS inkjet cartridge and labels** provide reliable printing and adhesion for syringe labeling.
- **Convenient label media and ink cartridge access** is provided for ease of replacing labels and ink.

Operational Features

- **Easy to service** with Codonics Return to Factory Warranty. An optional Express Warranty program is also available, which provides a replacement SLS if the problem cannot be solved by our Technical Support team. Also, the SmartDrive allows all configurations settings to be quickly transferred to a replacement SLS. This minimizes downtime and reconfiguration effort.

2

Setting Up the System

Finding a Location for the System

When finding a suitable location for the system, use the following guidelines:

- Place the system in a location with adequate air circulation to prevent internal heat build up.
- Do not place the system near heat sources such as radiators or air ducts, or in a location subject to direct sunlight, excessive dust, mechanical vibration, or shock.
- Do not block air ventilation at the rear of the system.
- Make sure that the countertop or work surface supporting the system is level, can support the weight, and will not vibrate or shake when the system is operating.
- The device has mounting holes designed to be compatible with VESA mounting capabilities. Refer to www.vesa.org for mounting options and instructions.

Shipped Components

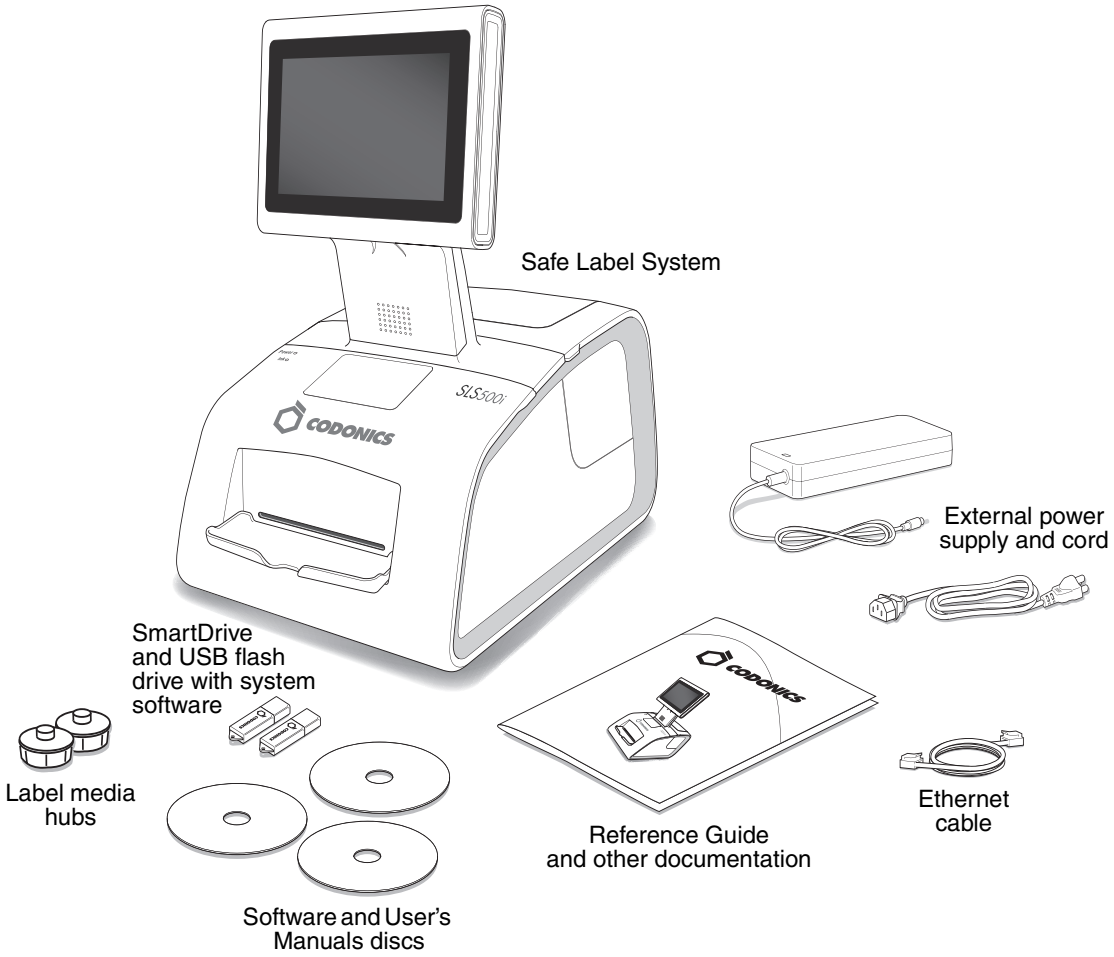
The SLS is shipped in cartons that contain the following system components:

- SLS
- Supporting documentation package (including the SLS Quick Reference, Warranty, and support documents)

The following items are found in the Accessory Kit box:

- Label media hubs
- External power supply and cord
- SmartDrive USB flash drive
- Ethernet cable (not currently used)
- Reference Guide and other printed documentation
- Software and User's Manuals disc

Some configurations also include a Starter Kit that has one ink cartridge and one label media.



Unpacked components

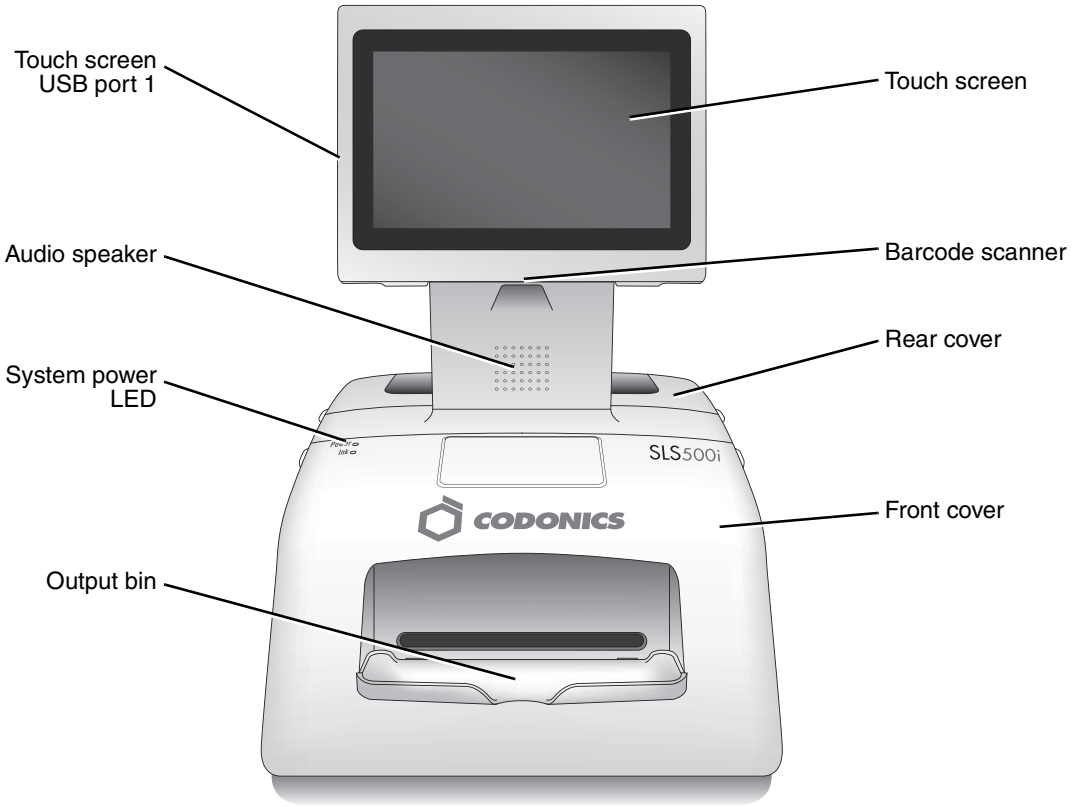
Inspect the cartons for damage that might have occurred during shipping. Report any damage to the shipping company.

Save the cartons and packing materials, in case you ever need to transport the SLS later.

CAUTION When removing the SLS, hold under the front and rear of the system. Do not lift the system by the foam packaging.

Identifying the Components

SLS Front Components



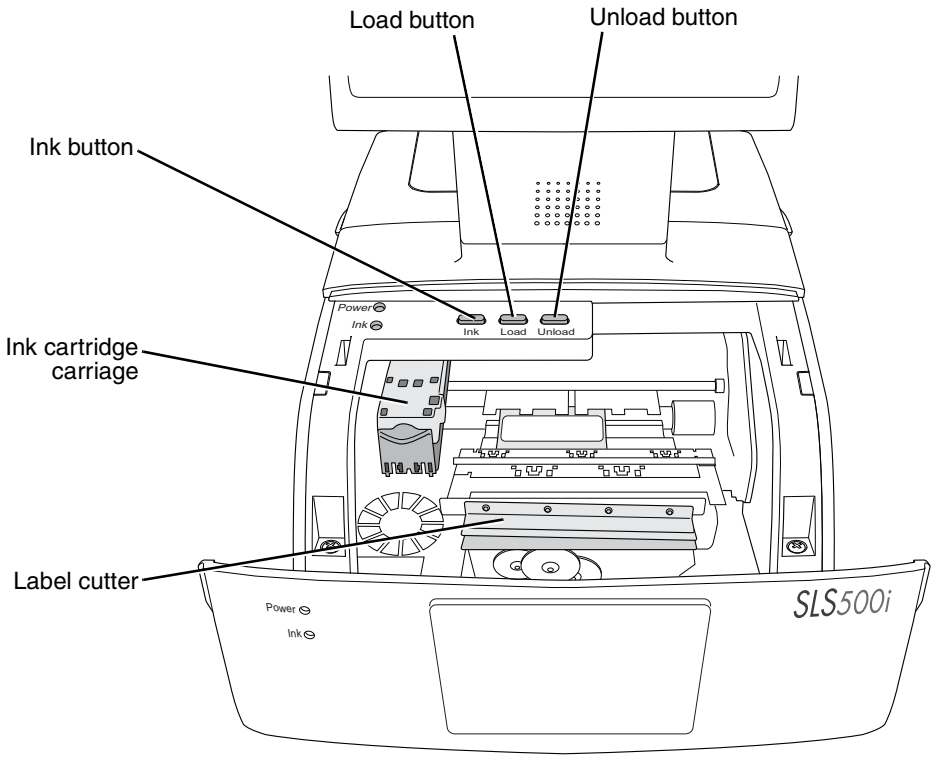
SLS front components

- The **Touch Screen** displays the user interface to the system.
- The **Touch Screen USB Port1** is used to install formulary update packages, configuration update packages, and software updates stored on USB flash drives.
- The **Audio Speaker** is used to announce drug names when a drug container's barcode is scanned, system messages, and other audio sounds.
- The **Barcode Scanner** scans drug container barcodes for identity and verification.
- The **Rear Cover** provides access to the label rolls.
- The **System Power LED** indicates when the system is powered on.
- The **Front Cover** is a durable plastic cover that protects the SLS from dust and accidental user interference while operating.

WARNING When the front cover is open, avoid contact with the label cutter.

- Printed labels are placed in the **Output Bin**.

Components Inside SLS Front Cover



Components inside SLS front cover

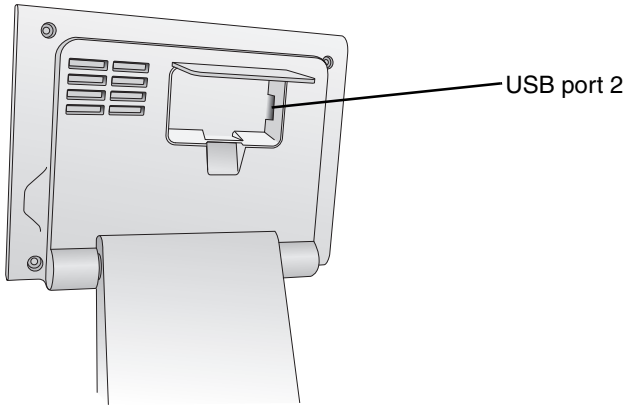
- Pressing the **Load Button** feeds the label media through the SLS and advances the labels.
- Pressing the **Ink Button** positions the ink cartridge carriage for easy ink cartridge replacement.

- Pressing the **Unload Button** unloads the installed label media by reversing it through the SLS.
- The **Ink Cartridge Carriage** holds the ink cartridge.
- The **Label Cutter** cuts the label after it is printed.

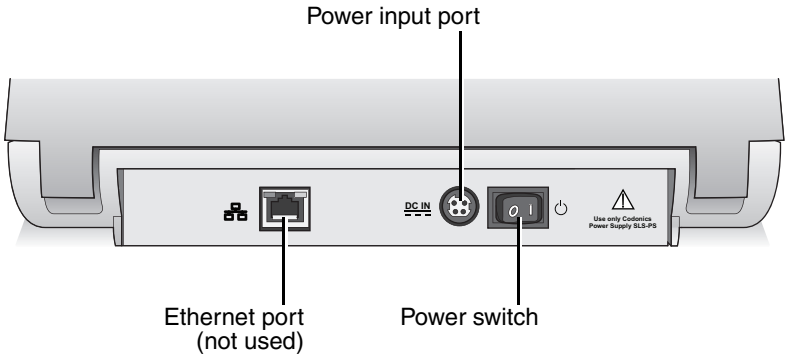
WARNING When the front cover is open, avoid contact with the label cutter.

SLS Rear Components

The following illustrations show the input/output ports and the power switch located at the rear of the SLS.



USB port 2, behind touch screen rear panel door



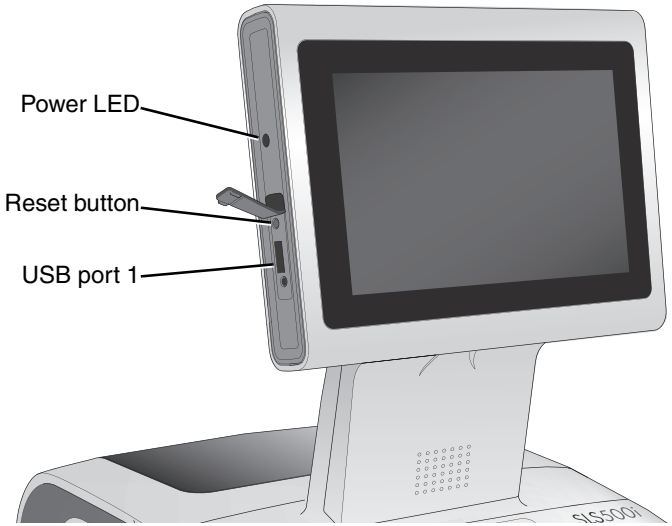
SLS rear panel power input port and Power switch

- **USB Port2**, behind the rear panel door, is used to mount the SmartDrive flash drive.
- The external power supply connects to the **Power Input Port**. The external power supply is a switching 100-V~240-V power supply.
- The **Power Switch** powers the SLS on and off.

NOTE: *The system includes an Ethernet port that is not currently supported and should not be used.*

Touch Screen

The following illustration shows the touch screen Power LED, the Reset button, and USB port 1 at the left side of the touch screen.



Reset button and USB port 1 at left side of touch screen

- The **Power LED** lights when the touch screen is powered on.
- The **Reset button** is used to reboot the system software in the event of a critical failure. If required, use a pen or other pointed tool to press the Reset button.

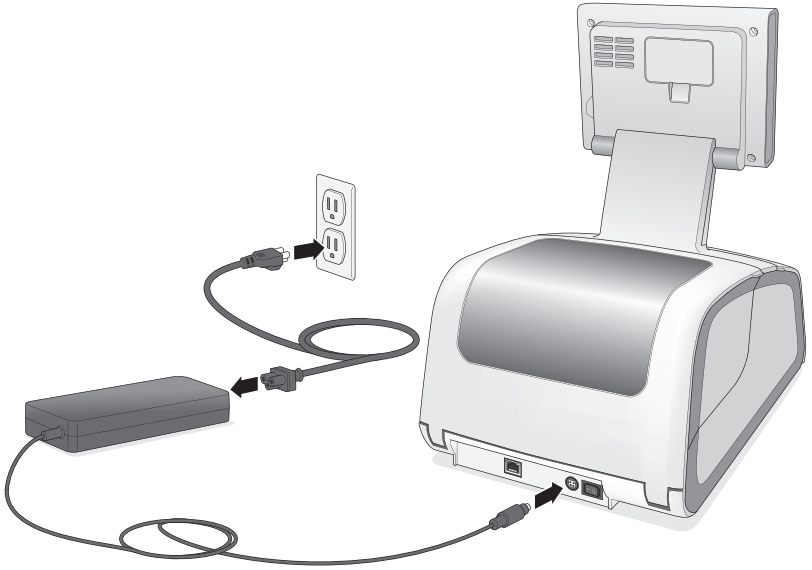
NOTE: *Do not use the Reset button unless directed to do so by Codonics Technical Support.*

- **USB port1** is used for connecting USB flash drives that contain software and formulary updates.

Connecting the External Power Supply

To connect the external power supply

1. Locate the external power supply included with your SLS.
2. Plug the external power supply into the Power Input port on the rear panel of the SLS.



Connecting the external power supply

3. Connect the power cord from the external power supply to a grounded power outlet that supplies the appropriate voltage for the applicable country.

WARNING The power cord plug is the main disconnect for the device. The power outlet should be near the device and be easily accessible.

WARNING Remove the power cord plug from the power outlet to disconnect overall power to the device.

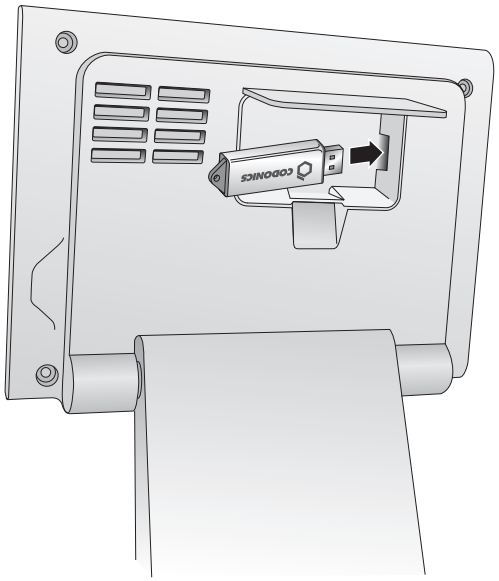
WARNING Grounding reliability can be achieved only when the SLS is connected to a receptacle marked "Hospital Only" (that is, "Hospital Grade").

Once the external power supply is connected, the SLS can be powered on and off using the Power switch on the rear panel.

Inserting the SmartDrive

To insert the SmartDrive

Insert the SmartDrive in USB port2 inside the touch screen rear panel door.



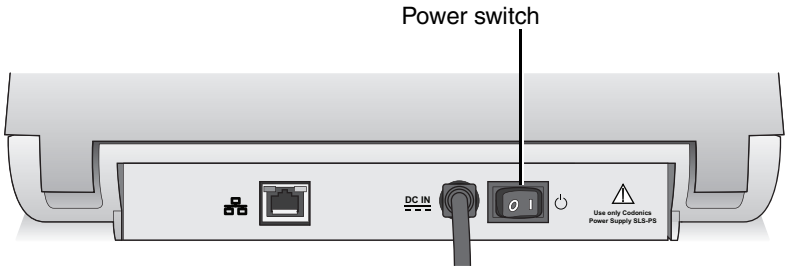
Inserting the SmartDrive into USB port 2 inside the touch screen rear panel door

NOTE: *The rear panel door is not intended to be removed.*

Starting Up the System

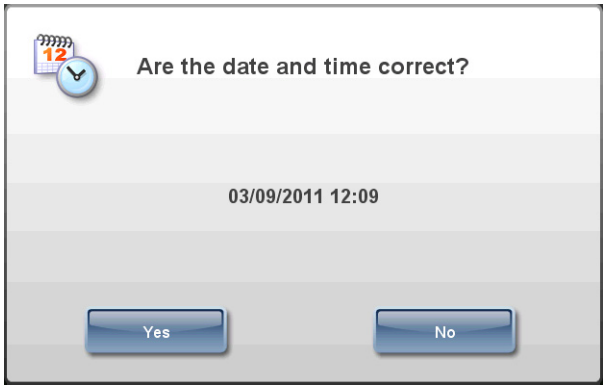
To start up the system

1. Press the Power switch on the rear of the SLS to power on and start up the system.



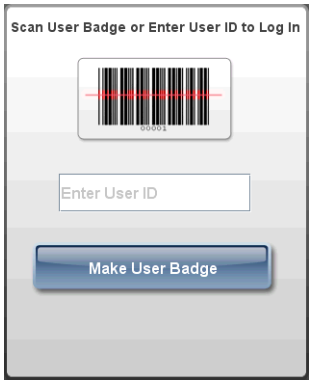
Power switch on the rear panel

When the SLS has completed its startup successfully, you are prompted to verify that the date and time are correct.



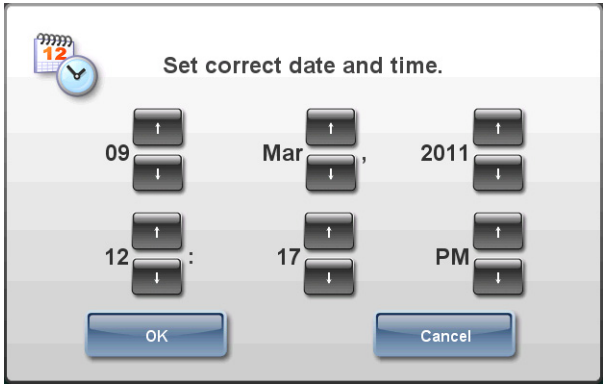
2. Press **Yes** if the date or time is correct.

   The Login screen displays.



   Press **No** if the date or time is incorrect.

   Controls for changing the date and time display.



3. Use the controls to correct the date and time, then press the **OK** button.

   The Login screen displays.

NOTE: *If the system detects that the SmartDrive contains a newer version of software, or that a USB flash drive contains an update package, you will be prompted to install the update. For more information, refer to "Installing Update Packages or System Software" on page 5-5.*

Installing the Ink Cartridge

The dashboard on the SLS touch screen indicates when there is a low ink condition: The System status light is yellow and the status message text reports that the system is low on ink.

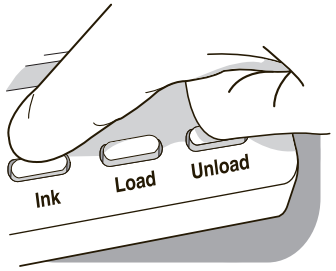
If there is no ink, the System status light will be red. During setup, this will be the condition until the ink cartridge is installed.

NOTE: *The SLS is designed to work only with Codonics ink cartridges. To order ink cartridges, refer to "Ordering Supplies and Parts" on page 5-1. Using unapproved ink cartridges could lead to poor print quality and incorrect label colors.*

NOTE: *Never refill ink cartridges, as this can result in incorrect color usage and cause improperly printed labels.*

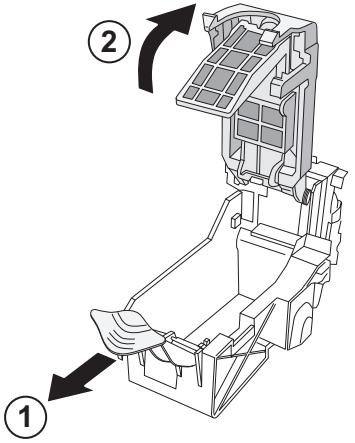
To install an ink cartridge

1. Open the front cover.
2. Press the Ink button.



Ink button

3. Open the carriage cover by pulling out on the purple hold-down clip. The cover is spring-loaded and will pop open.

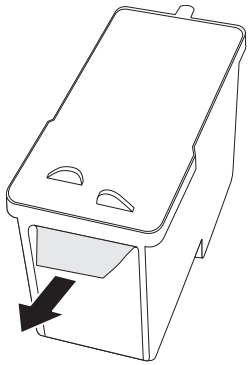


Opening the ink cartridge carriage cover

4. Remove the ink cartridge from its packaging.

   Once the ink cartridge is removed from its package, hold it by its sides.

5. Slowly remove the tape covering the cartridge's print head.

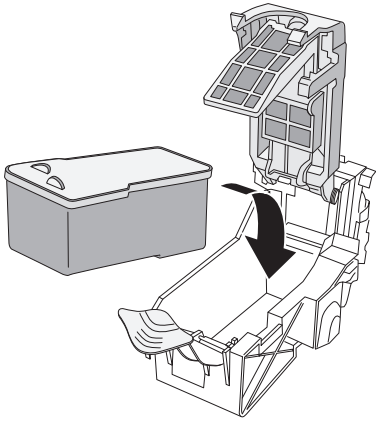


Removing ink cartridge print head tape

CAUTION Do not touch the copper area of the cartridge print head.

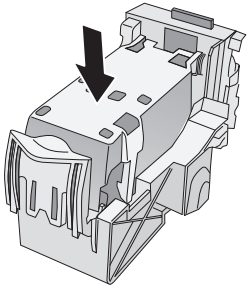
6. Insert the ink cartridge into its carriage, copper end first.

   Hold the cartridge at a 45º angle as you slide it into its carriage, then tilt the cartridge down until it fully drops into place.



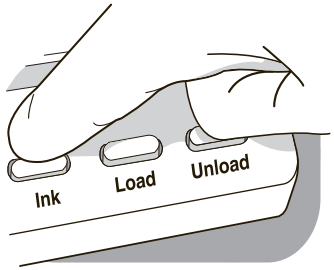
Loading the ink cartridge

7. Close the carriage cover until it snaps into place and is secured by the purple hold-down clip.



Carriage cover closed

8. Press the Ink button.



Ink button

9. Close the front cover.

Loading or Replacing the Label Media

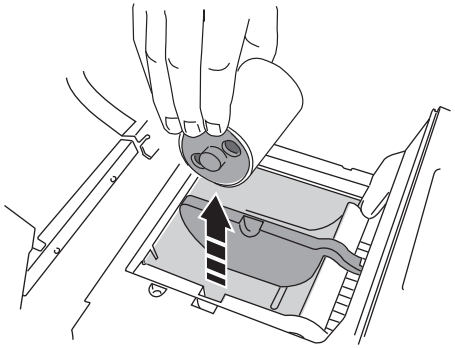
NOTE: *Use only Codonics labels to ensure proper operation of the device and proper labeling of syringes. Using unapproved labels could lead to unacceptable results, including poor print quality and poor label adhesion to the syringe.*

NOTE: *Unwanted labels should be destroyed or disposed of to ensure that improper labels are not used.*

To load or replace label media

1. Open the rear cover.
2. Optionally, remove the rear cover. For more information, refer to "Removing the Rear Cover" on page 5-8

3. Remove the loaded label media and hubs from the media guides.

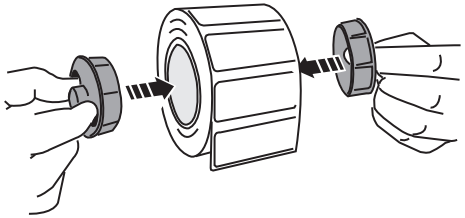


Removing the loaded label media

4. Remove any shipping tape or rubber bands from the new label media to ensure that it can unroll freely, making certain that no adhesive portion is exposed.

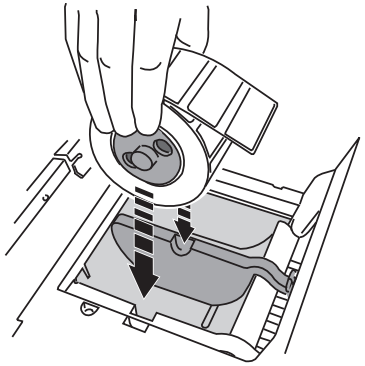
NOTE: *Any exposed adhesive surface can attach itself to the inner workings of the print mechanism and cause a label jam.*

5. Insert the hubs into the label media.



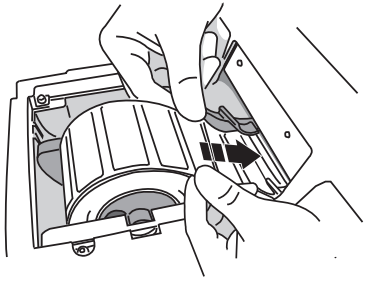
Inserting the hubs into the label media

6. Place the label media with hubs into the media guides.

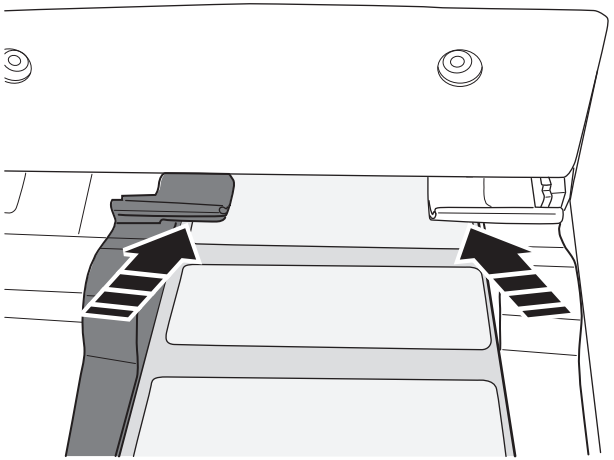


Placing the label media with hubs into the media guides

7. Adjust the media guides into position to securely hold the label media while allowing it to turn freely.
8. Place the leading edge of the label media below the two top media guides and into the feeder slot.



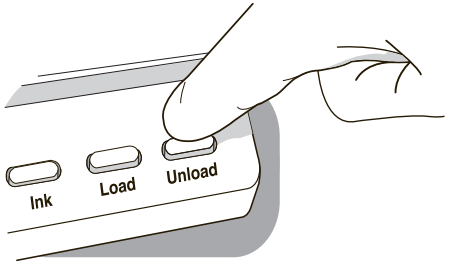
Placing the label media leading edge into the feeder slot



Label media fed beneath media guides

9. Feed the label media leading edge further into the feeder slot until the SLS senses the labels and automatically feeds them through. You might need to hold the label media in place for a few seconds.

NOTE: *If the SLS fails to feed the label media, open the front cover, press the Unload button (shown below), remove the media from the media path, wait until the media path rollers stop spinning, and try loading the media again.*



Unload button

SmartDrive and Stored Information

The SLS SmartDrive is a USB flash drive that holds critical SLS information, including configuration data and log files.

CAUTION The SmartDrive must be inserted for the system to operate. If the SmartDrive is not inserted, the system can start up but will not be able to process jobs. A message at the touch screen will prompt you to insert the SmartDrive.

The SmartDrive also allows you to move the configuration files of one SLS to another SLS, thus allowing the second SLS to operate exactly like the first. This feature is especially helpful when swapping an SLS for service purposes.

NOTE: *A SmartDrive cannot be duplicated. That is, it cannot be used in two SLS units at the same time.*

Information Stored on the SmartDrive

The SLS SmartDrive stores the following information:

- **The SLS Software License Code**. This is the serial number for the SLS software. All keyed features are keyed from the License Code.
- **The SLS Configuration**. This includes all of the system's configuration settings.
- **Formulary database.** This is a backup copy of the formulary database that is stored in the SLS.
- **Tracking database.** This is the database that is used to track user events (for example, when a user logs on or off the system, or when a user prints a label).

- **Log files.** These include installation logs, system logs, and event audit logs.

The SLS configuration, formulary database, tracking database and log files that are stored on the SmartDrive are encrypted to ensure the security of the data.

Events That Synchronize Data to the SmartDrive

The following events trigger a synchronization of the SLS data with that stored on the SmartDrive:

- Automatically every 15 minutes
- Shutting down the system
- Formulary updates

3

Basic Operations

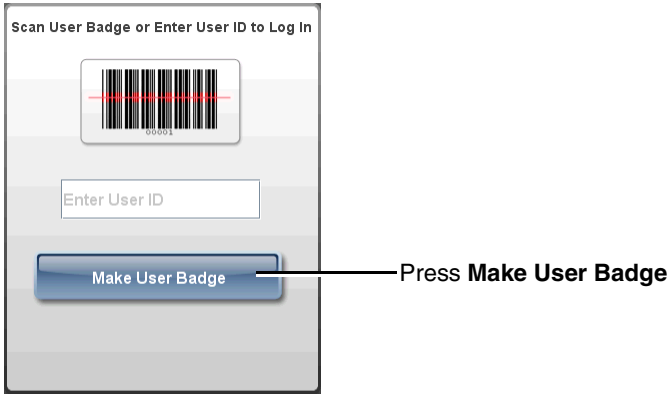
CAUTION Users should read and understand all safety warnings and operating instructions prior to using the system.

Making a User Badge

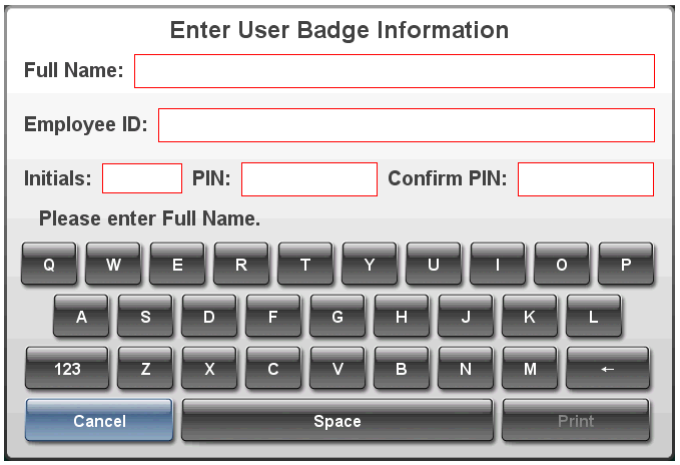
At the Login prompt, you can choose to make and print a user badge for yourself. You can then log in to any SLS by scanning the barcode on the badge. If you have already made a badge and just need to reprint it, refer to "Printing a User Badge" on page 3-15.

To make a user badge

1. At the Login prompt, press the **Make User Badge** button.



You are prompted to enter your user information.



2. Enter user information by pressing each field and using the on-screen keyboard.

NOTE: *The PIN can be up to ten digits long. If the system is not configured to require a PIN, then you will not be prompted to enter one.*

3. When you have entered your user information, press the **Print** button.

   The badge is printed and placed in the output bin. The Login prompt is displayed.

   Your user information is stored in the system. You can now use this badge to log in to any SLS by scanning its barcode.

NOTE: *If you make a badge and had previously made one, your user information is overwritten with the most recent entry.*

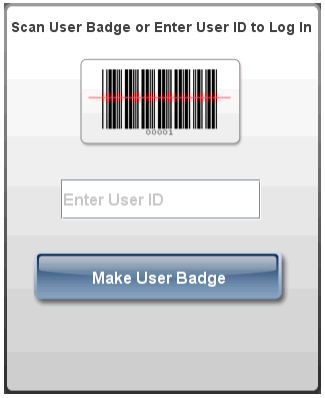
NOTE: *The SLS system administrator needs to ensure that unique user IDs are assigned to each user.*

Logging In

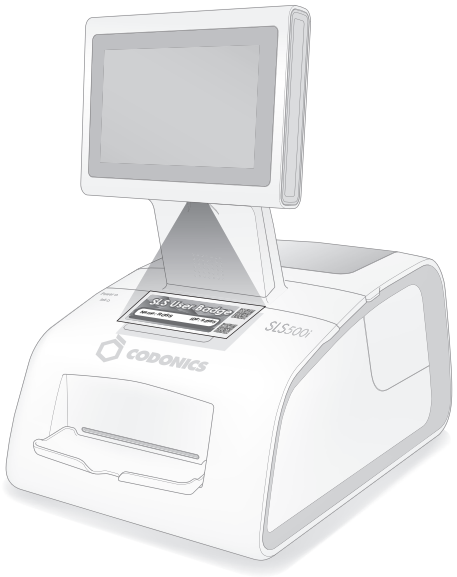
You log in by entering your user ID or by scanning the barcode on your user badge. For information about making a user badge, refer to “Making a User Badge” on page 3-1.

To log in

1. With the Login prompt displayed, enter your user ID using one of the following methods:



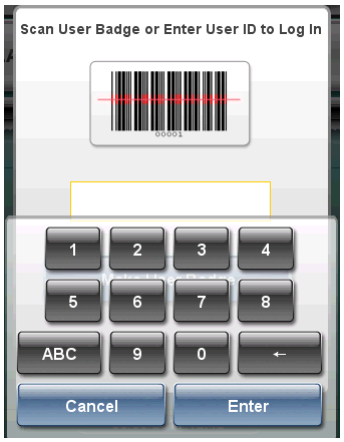
- Method 1: Press the **Enter User ID** field. Then go to step 2.
- Method 2: Scan the barcode on your user badge.



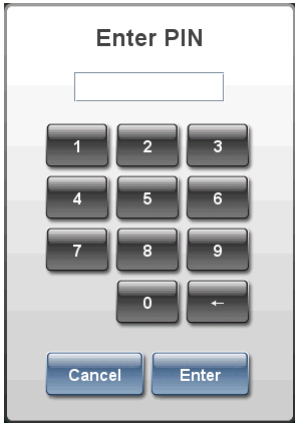
Scanning a user badge

If the SLS has been configured to require a PIN, you are prompted to enter your PIN, which can be up to ten digits long. Go to step 3. Otherwise, a test label is printed and you are prompted to confirm that it printed correctly (the prompt is shown in step 3). Go to step 4.

2. Use the keypad to enter your user ID, and then press the **Enter** button.

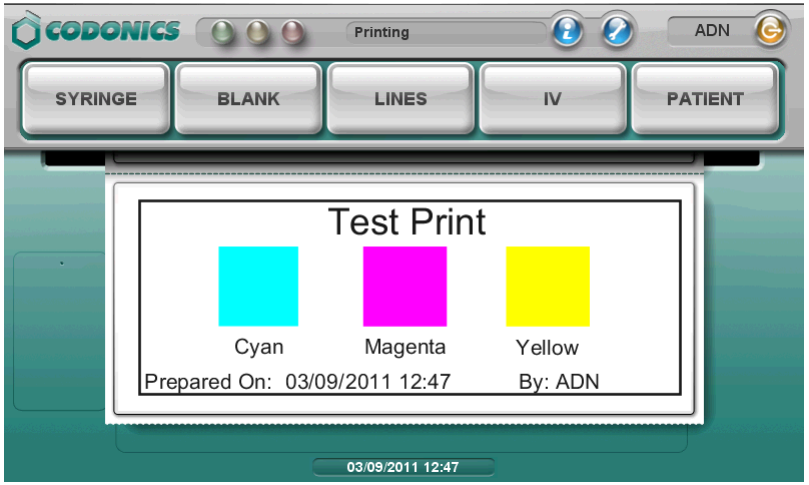


If the SLS has been configured to require a PIN, you are prompted to enter your PIN, which can be up to ten digits long. Otherwise, a test label is printed and you are prompted to confirm that it printed correctly (the prompt is shown in step 3). Go to step 4.



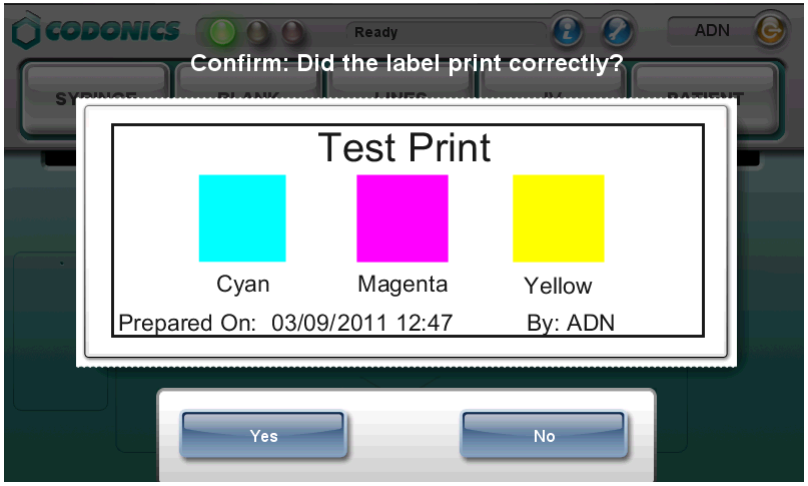
3. Enter your PIN and then press the **Enter** button.

   To ensure that labels print properly, the test print screen displays and a test label is printed.



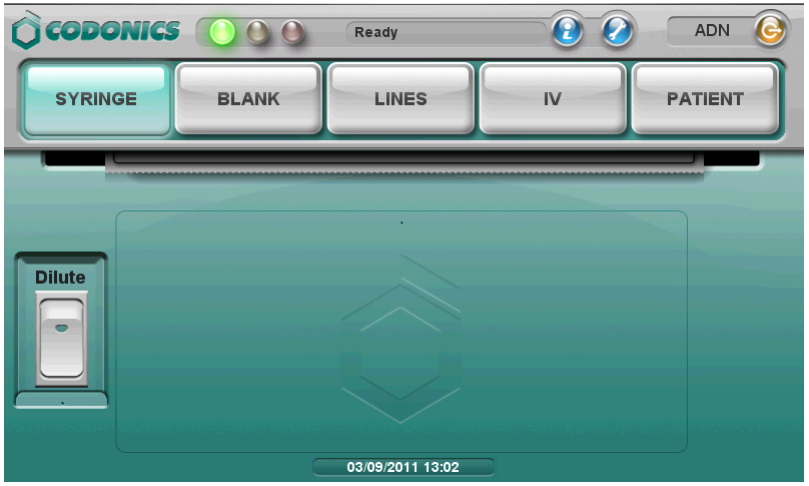
NOTE: *The system will ensure that a test print is performed at least once a day.*

You are then prompted to confirm the test label printed correctly.



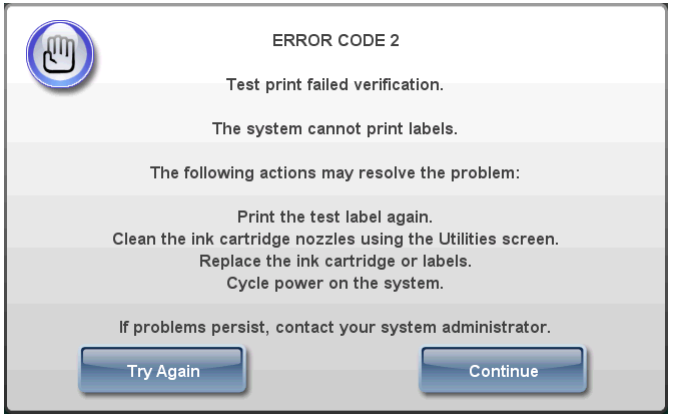
4. Review the following to ensure that the test label printed correctly:
   - The colors are correct
   - The label content is correctly centered
   - The print is not faded
   - There is no horizontal banding
   - The date and time are correct
   - The user's initials are correct
5. If the test label has printed correctly, press the **Yes** button.

The main screen displays and the system is ready for use.



If the test label prints incorrectly, press the **No** button.

A Test Print Failed Verification message displays.



6. **To print another test label,** press the **Try Again** button.

   Another test label prints and you are prompted again to confirm the test label.

   To attempt to resolve the printing problem, press the **Continue** button.

   The Utilities screen displays and the SLS is put into an out-of-service state.

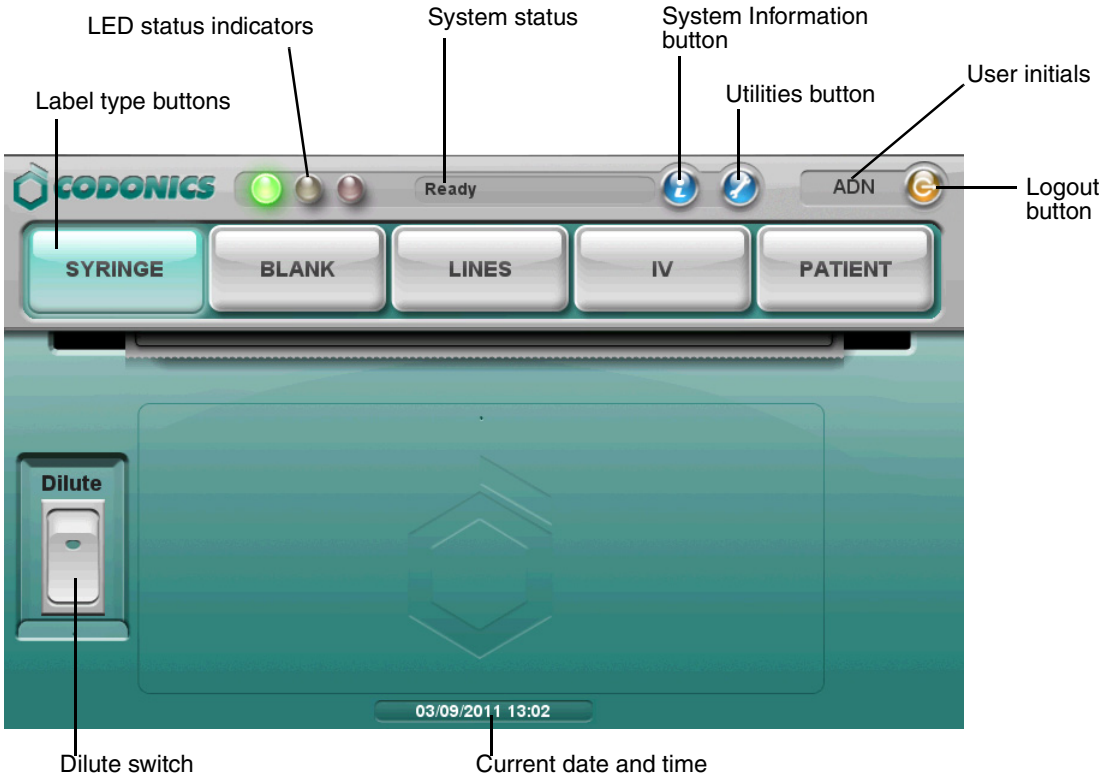
7. To troubleshoot the printing problem and perform the recommended solution, refer to Table 6-1 on page 6-7.

   The system cannot leave the out-of-service state until you press the **Yes** button in response to the prompt to confirm that the test label printed correctly. So, after each solution you try, print another test label. If the utility you use does not do this automatically, you can log out and log in again to have the system print a test label.

8. If the test label still does not print correctly after trying the suggested solutions, contact your SLS system administrator.

Touch Screen User Interface

The elements of the main screen are identified in the following figure.



SLS Utilities

You can perform the following operations from the Utilities screen:

- Adjusting the audio volume
- Adjusting the touch screen brightness
- Printing another copy of your user badge

There are other utilities that are used to maintain the SLS and that are described in other chapters in this User's Manual:

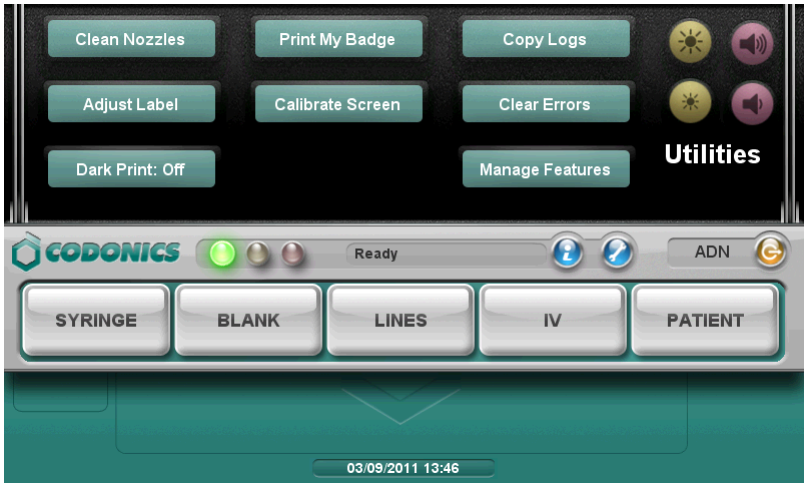
- Cleaning the ink cartridge nozzles. Refer to "Cleaning the Ink Cartridge Nozzles" on page 6-23.
- Adjusting the label media path. Refer to "Adjusting the Media Path" on page 6-26.
- Setting the black levels of a printed label. Refer to "Adjusting the Label Black Levels" on page 6-28.
- Calibrating the touch screen. Refer to "Calibrating the Touch Screen" on page 5-9.
- Copying system log files to a USB flash drive. Refer to "Backing Up Log Files" on page 5-12.
- Clearing system errors. Refer to "Clearing Errors" on page 6-30.
- Adding SLS features. Refer to "Adding a Feature" on page 5-15.

Displaying the Utilities Screen

To display the Utilities screen

Press the **Utilities** button.

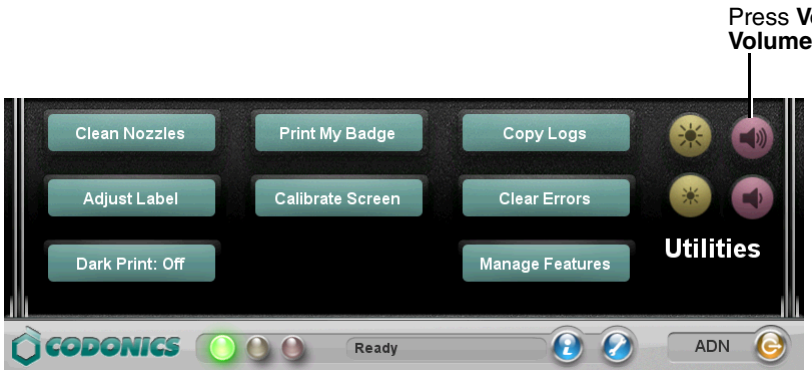
The Utilities screen displays.



Adjusting the Audio Volume

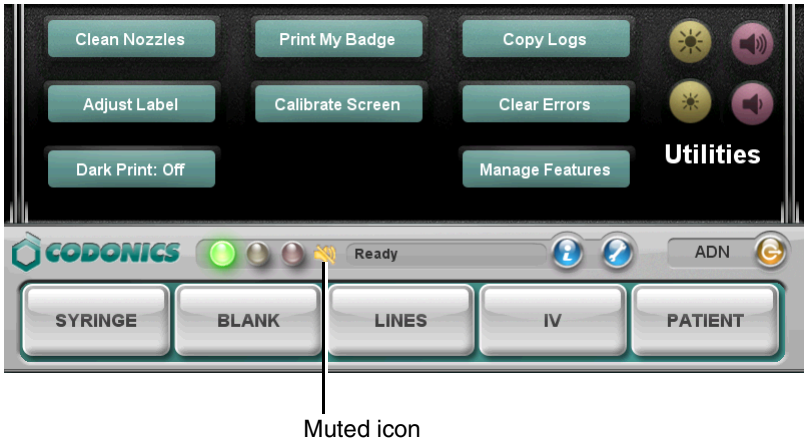
To adjust the audio volume

Press the **Volume Up** or **Volume Down** button.



The current volume level is indicated by an audible beep and in the volume level display.

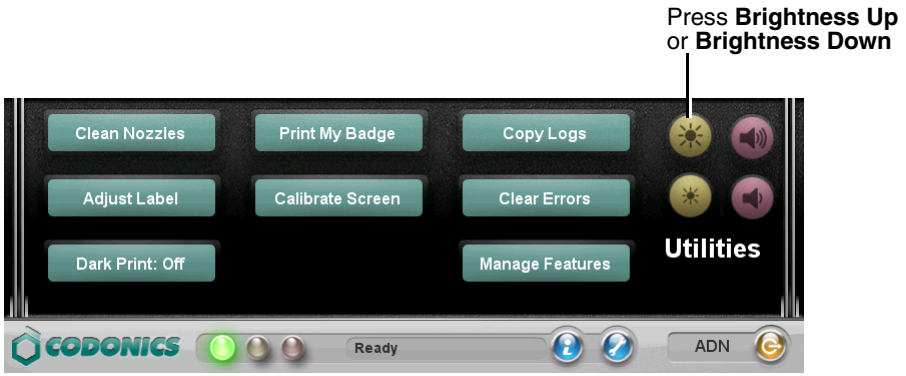
If you turn the volume down until it is muted, and a Muted icon displays in the Dashboard.



Adjusting the Touch Screen Brightness

To adjust the brightness

Press the **Brightness Up** or **Brightness Down** button.



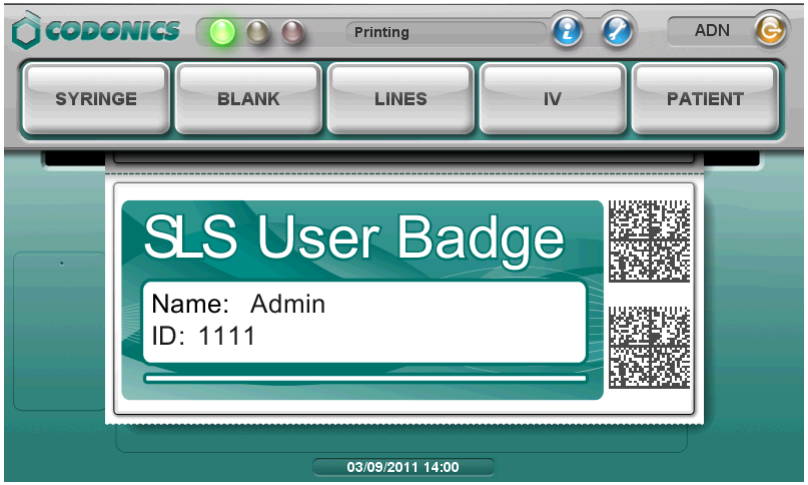
The current brightness level is indicated by the brightness level display.

Printing a User Badge

To print a user badge

Press the **Print My Badge** button.

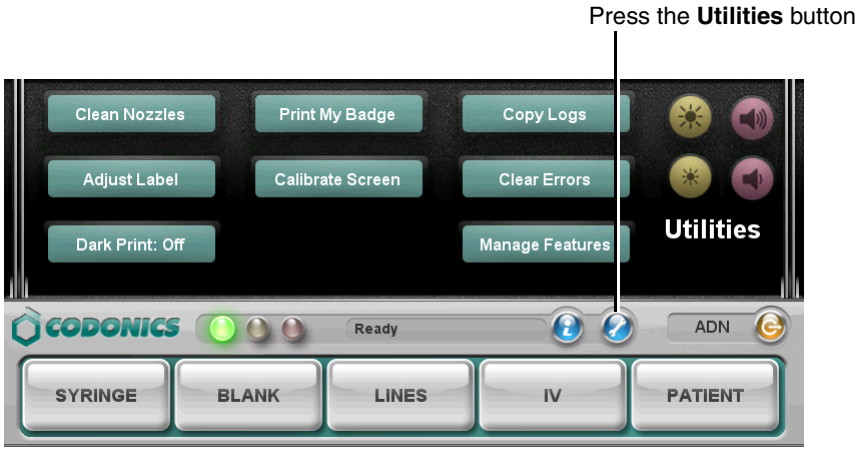
The user badge is displayed and then printed.



Closing the Utilities screen

To close the Utilities screen

Press the **Utilities** button.



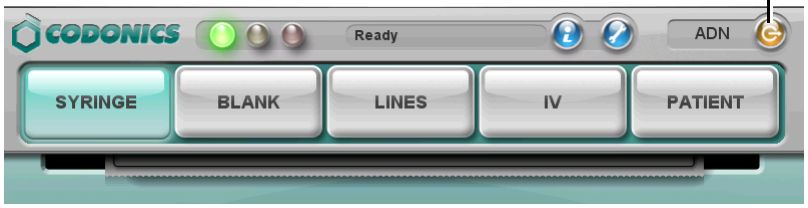
The Utilities screen closes.

Logging Out

To log out

1. Press the **Logout** button.

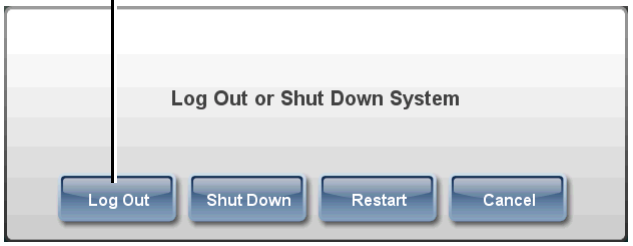
Logout button



The **Log Out or Shut Down** dialog box displays.

2. Press the **Log Out** button.

Logout button



The Login prompt displays.

Being Logged Out Automatically Due to Inactivity

The system includes a preconfigured timeout period (by default, 15 minutes) to help ensure the security of system operations.

If a user is logged in but the user session is idle for the timeout period, a notification message displays and a countdown begins.

To cancel the automatic logout and continue with your session, press the **Continue** button. The system resets the inactivity timer.

Screen Blanking Due to Inactivity

If the system is inactive for a preconfigured timeout period (20 minutes), the touch screen becomes blank. To reactive the system, press anywhere on the touch screen and the display will activate again.

Shutting Down or Restarting the System

You should always shut down the system software before powering down the system.

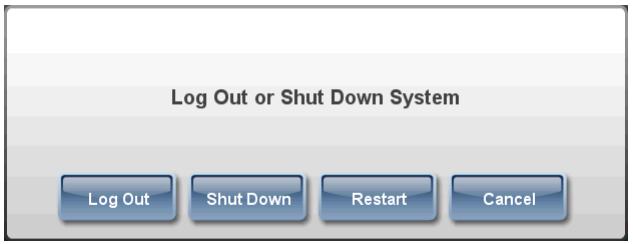
CAUTION Always make sure that all print jobs have completed before shutting down or restarting the system software.

Before attempting to shut down or restart the system, make sure that all print jobs have finished.

To shut down or restart the system software

1. Make sure all print jobs have completed.
2. Press the **Logout** button.

The **Log Out or Shut Down** dialog box displays.



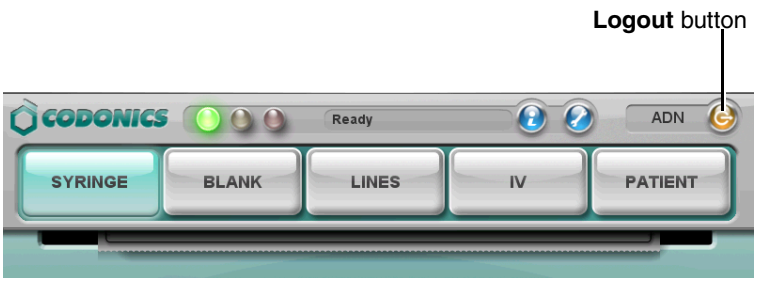
3. Press the **Shut Down** or **Restart** button.

   The system shuts down or restarts.

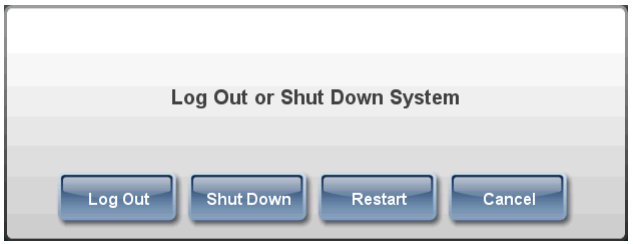
Powering Off the System

To power off the system

1. Make sure all print jobs have completed.
2. Press the Logout button.



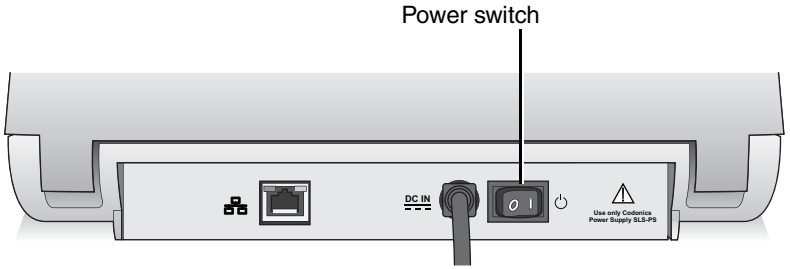
The Log Out or Shut Down dialog box displays.



3. Press the Shut Down button.

   The system shuts down and displays a message indicating that it is now safe to power off the system.

4. Set the Power switch on the rear panel to off.



Power switch on the rear panel

CAUTION Always make sure that the user is logged out of the session and all print jobs have completed before shutting down or restarting the system software. Make sure that the device is properly powered off to allow the ink cartridge to be sufficiently capped.

4

Printing Labels

Overview

The SLS allows you to scan a drug's barcode and easily print a label containing information about the drug, the preparer, the time of preparation, and other information (for example, concentration, dilution notice, user defined warnings, expiration times), to be affixed to a syringe. It also allows you to print custom labels that have been configured for your site.

Formulary Database

Information about scanned drugs is contained in the formulary database that was installed on the SLS. The formulary database is managed by an administrator using the SLS Administration Tool. For more information about the Administration Tool, refer to the SLS Administration Tool User's Manual.

Each drug record in the formulary database contains use and labeling information, audio announcements that are played when the drug record is found, whether the dilution should be forced or not allowed for the drug, and a choice of concentrations and diluents.

To ensure safety, no changes are ever written to the formulary database in the SLS and all formulary updates are handled by a full overwrite of the database.

Container IDs (Outside the USA)

Outside the USA, Container IDs are used to identify drugs. A drug's Container ID is included in its container barcode.

When you scan a drug container to initiate the printing of a syringe label, the SLS uses the Container ID to find the correct drug information in the formulary database.

Container IDs and Master IDs (USA Only)

In the USA, 11-digit Master IDs and 10-digit Container IDs are used to identify drugs. A drug's Container ID is included in its container barcode.

Master IDs always uniquely identify a drug. However, in rare cases, the same Container ID could be used for up to three different drugs.

When you scan a drug container barcode to initiate the printing of a syringe label, the SLS uses the Container ID to find the correct drug information in the formulary database. The SLS looks for drugs with the same Container ID and for Master IDs that map to the Container ID. The Master ID can be used to help locate the correct drug record when the Container ID is not in the formulary database.

Matching Container IDs

Matching is the process that occurs when a drug container barcode is scanned on an SLS and the SLS determines that the Container ID in the barcode equals (that is, *matches*) the Container ID for one or more drug records in the formulary database.

Mapping Container IDs to Master IDs (USA Only)

Mapping is the process that occurs when a drug container barcode is scanned and there are 11-digit Master IDs that could potentially map to the scanned 10-digit Container ID.

Learning is the process of associating the 10-digit Container ID with one of the mapped 11-digit Master IDs.

For more information about mapping and learning, refer to "Learning a Drug (USA Only)" on page 4-8.

Verification

Verification is the process of scanning a drug container's barcode and verifying that the drug name and concentration that is in the formulary database matches the drug name and concentration of the scanned drug container. For more information, refer to "Verifying a Drug" on page 4-10.

Printing a Syringe Label

The general workflow for printing a syringe label is:

1. If you want to specify the drug's dilution, set the Dilution switch to on.
2. Scan the drug container barcode.
3. Specify the dilution and diluent, if necessary.
4. Confirm the label displayed on the touch screen before printing it, if this confirmation step has been configured.
5. Retrieve the printed syringe label from the output bin.
6. Confirm whether the syringe label printed correctly, if this confirmation step has been configured.

Details for these steps are covered in the following topics.

CAUTION The formulary used on the SLS should be one that was created by the system administrator and approved for use.

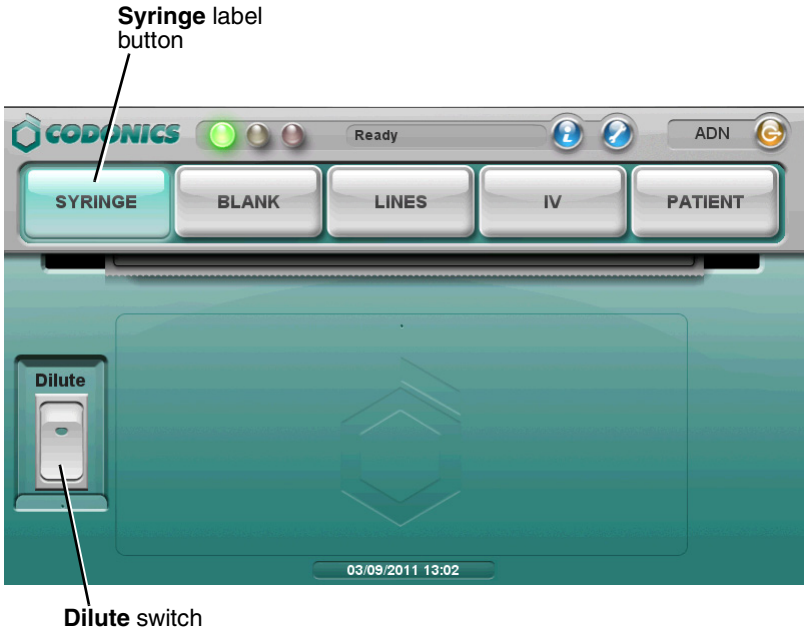
CAUTION When preparing syringes, always keep control of the drug container and syringe until the label is properly printed, confirmed, and adhered to the proper syringe.

NOTE: *It is recommended that syringes smaller than 5 cc (ml) have the printed label wrapped around the barrel of the syringe with the ends adhered together in a flag fashion.*

Scanning the Drug Container Barcode

To scan the drug container barcode

1. Press the **Syringe** label button.



2. To include dilution information on the label for drugs that can be diluted, press the **Dilute** switch to on. This must be done prior to scanning the drug container barcode.

NOTE: *The dilution setting for each drug in the formulary has precedence over the* ***Dilute*** *switch setting. Therefore, the* ***Dilute*** *switch will be ignored if the drug is not allowed to be diluted or if it is required to be diluted. For more information about determining a drug's dilution setting in the formulary, refer to the SLS Administration Tool User's Manual.*

NOTE: *The* ***Dilute*** *switch is set to off at the completion of the label printing.*

3. Scan the drug container barcode by aligning the barcode with the barcode scanner located below the touch screen.

Scanning a barcode on a drug container

NOTE: *Place the container below the scanner so that the red cross-hair lines up on the barcode. Placing the container closer to the cover, almost resting it on the cover, instead of placing it closer to the scanner, will also provide better results.*

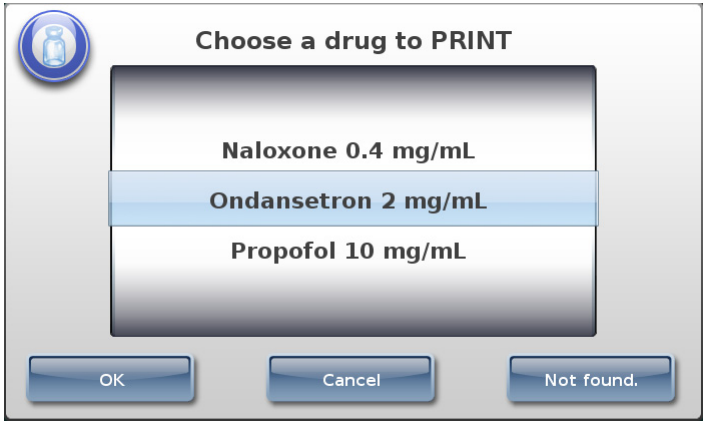
Selecting from Matching Container IDs

Matching is the process that occurs when a drug container barcode is scanned on an SLS and the SLS determines that the Container ID in the barcode equals (that is, *matches*) the Container ID for one or more drug records in the formulary database.

For single matches, the matching drug record is automatically selected by the system.

In very rare instances, if more than one match is found, the matching drugs are listed in the **Choose a drug to PRINT** dialog box, as shown below.

NOTE: *If there are multiple matches for a Container ID, this dialog box will be displayed every time a drug container barcode with that Container ID is scanned.*



You have three options:

- If none of the choices are correct, press the **Not Found** button. The system indicates that no drugs were selected and a syringe label is not printed.

  Or, in the USA, if mappings are then found after pressing the **Not Found** button, then the **Choose a drug to LEARN** dialog box displays. Refer to "Learning a Drug (USA Only)" on page 4-8.

- To cancel the print operation, press the **Cancel** button. The main screen displays.
- If one of the choices is correct, select it and press the **OK** button. A confirmation dialog box displays.

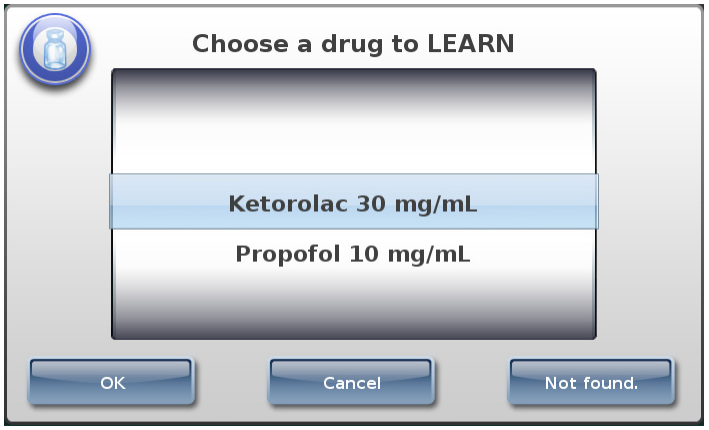
Learning a Drug (USA Only)

Mapping is the process that occurs when a drug container barcode is scanned and there are 11-digit Master IDs that could potentially map to the scanned 10-digit Container ID.

For example, a pharmacist enters only a drug's 11-digit Master ID when adding the drug to the formulary. When a user scans that drug's container barcode for the first time and there are no 10-digit Container ID matches, the SLS will look for all 11-digit Master IDs that could potentially map to the drug's Container ID.

Learning is the process of associating the 10-digit Container ID from a scanned drug container barcode with a mapped 11-digit Master ID.

If the Container ID has mappings in the formulary database, then any Master ID mappings that are found for the Container ID are displayed in the **Choose a drug to LEARN** dialog box.



You have three options:

- If none of the choices are correct, press the **Not Found** button. The system indicates that no drugs were selected and a syringe label is not printed. A custom label can then be selected for printing.
- To cancel the print operation, press the **Cancel** button. The main screen displays.
- If one of the choices is correct, select it and press the **OK** button. A confirmation dialog box displays.

The drug has been learned by the system. The next time this drug container barcode is scanned, the system will remember the correct drug information to use.

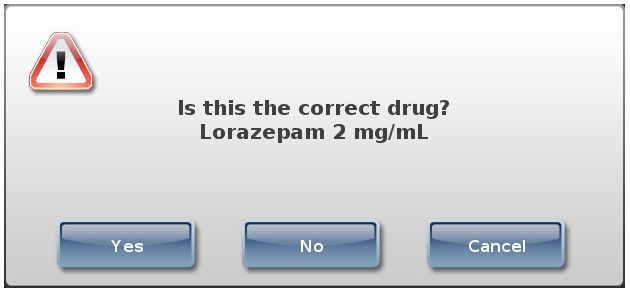
CAUTION SLS users can have an SLS learn drug containers. Please contact your SLS system administrator for proper training and usage.

NOTE: *Learned drugs are added only to the individual SLS. Global updates should be made in the Master Drug Database (MDD) and formulary using the Administration Tool. For more information, refer to the SLS Administration Tool User's Manual.*

Verifying a Drug

Verification is the process of scanning a drug container's barcode and verifying that the drug name and concentration that is in the formulary database match the drug name and concentration of the drug container. By default, each SLS requires that all scanned drug containers be verified the first time that each SLS sees them. Refer to the SLS Administration Tool User's Manual for more information about verification configuration.

If a drug's verification status is Not Verified, then the verification prompt displays.

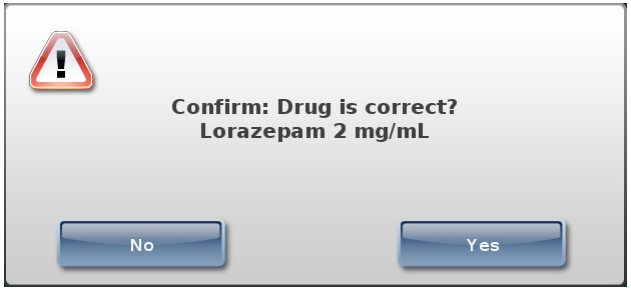


You have three options:

- If the displayed information does not match the drug container, press the **No** button. The system prompts you to confirm your decision. If you confirm it, then the system indicates that the drug failed verification and you are given the option of printing a custom label. You could then enter the syringe drug information on the custom label by hand. If this drug container barcode is scanned again at this SLS, the system will indicate that the drug has a Verification Failed status and will only allow the option of printing a custom blank label. For more information about custom labels, refer to "Custom Labels" on page 4-18.

CAUTION A failed verification is a serious issue. It means that the formulary is wrong. An SLS system administrator should be consulted immediately to review the logs and correct the formulary.

- To cancel the print operation, press the **Cancel** button. The main screen displays.
- If the displayed information matches the drug container, press the **Yes** button. The system prompts you to confirm your decision.



To confirm your decision, press the **Yes** button.

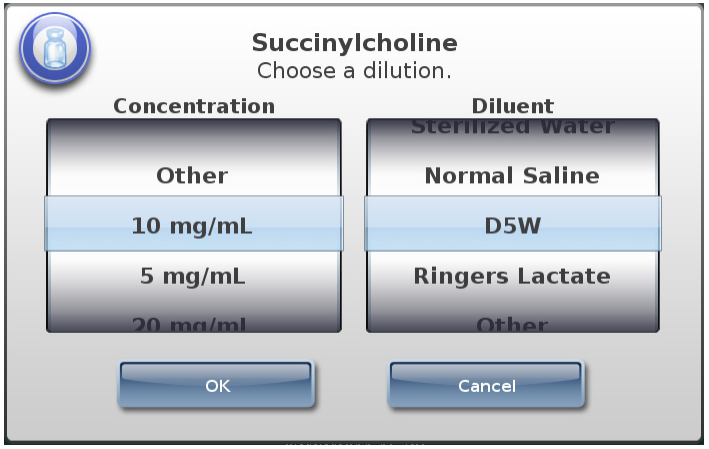
By default, each SLS requires that all scanned drug containers are to be verified the first time that each SLS sees them. Refer to the SLS Administration Tool User's Manual for more information about verification configuration.

CAUTION SLS users can verify drug containers. Please contact your SLS system administrator for proper training and usage.

NOTE: *If a drug record in a formulary is Not Verified, that drug will have to be verified on each of the SLSs on which the formulary is installed. Verifying a drug record in one SLS does not change its verification state in the other SLSs.*

Specifying the Dilution and Diluent

If you turned the **Dilute** switch on and the drug can be diluted, or if the drug must be diluted, you are prompted to specify the dilution and diluent.



Press and/or drag the lists until the appropriate concentration (dilution) and diluent are selected (that is, they are displayed under the blue highlighted bars)

You can also select **Other** for the concentration to print a label with a blank line so that you can enter the dilution on the label by hand. You can also select **Other** for the diluent.

WARNING SLS users are responsible for calculating the correct dilution/concentration.

NOTE: *Additional dilutions can be added using the SLS Administration Tool. For more information, refer to the SLS Administration Tool User's Manual.*

After selecting the concentration and diluent, press the **OK** button. One of the following occurs:

- You are prompted to confirm the label before it is printed, if this option has been configured. Go to "Confirming the Syringe Label Before Printing It" on page 4-14.
- The label is printed. Retrieve the label and go to "Confirming the Printed Syringe Label" on page 4-16.

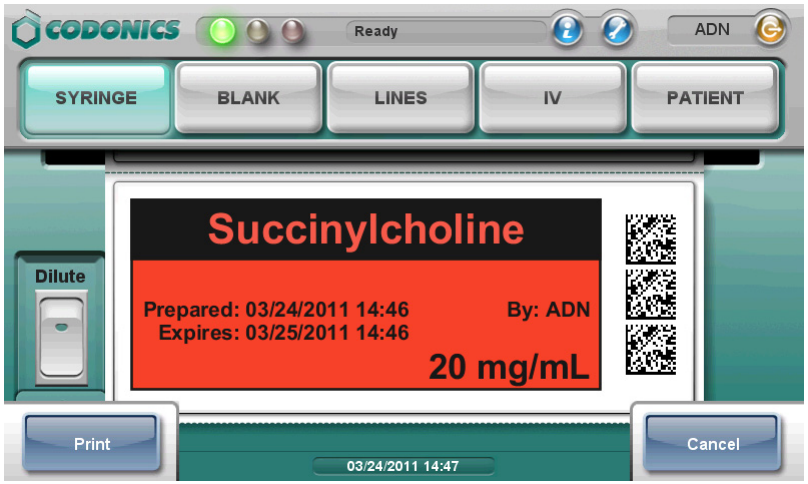
WARNING To avoid mislabeling syringes, make sure that you immediately remove each label from the output bin after it is printed, confirm the label, and then affix it to the appropriate syringe before attempting to print another syringe label.

WARNING Unwanted labels should be destroyed or disposed of to ensure that incorrect labels are not used.

Confirming the Syringe Label Before Printing It

If the system is configured to require visual confirmation of the label before printing it, you are prompted to confirm the displayed label.

NOTE: *If a sound file has been configured for the scanned drug, the system also announces the drug name and, if specified, the concentration when the label to be printed is displayed on the main screen.*



NOTE: *Labels as presented on the touch screen and in print form might not be an absolute match to how your SLS system administrator viewed them in the Administration Tool.*

If the label is not correct or you do not want to print the label at this time, press the **Cancel** button.

CAUTION A failed visual label confirmation is a serious issue. It means that the formulary is wrong. An SLS system administrator should be consulted immediately to review the logs and correct the formulary.

If the label is correct, press the **Print** button to confirm it and print the label. After the label has been printed, retrieve it from the output bin.

WARNING To avoid mislabeling syringes, make sure that you immediately remove each label from the output bin after it is printed, confirm the label, and then affix it to the appropriate syringe before attempting to print another syringe label.

WARNING Unwanted labels should be destroyed or disposed of to ensure that incorrect labels are not used.

Next you need to confirm that the label printed correctly. Go to "Confirming the Printed Syringe Label" below.

Confirming the Printed Syringe Label

If the system is configured to require confirmation of the printed syringe label, you are prompted to scan the label's barcode to confirm that it printed correctly.

NOTE: *Labels as presented on the touch screen and in print form might not be an absolute match to how your SLS system administrator viewed them in the Administration Tool.*

After reviewing the printed label and the label displayed on the touch screen, you have the following options:

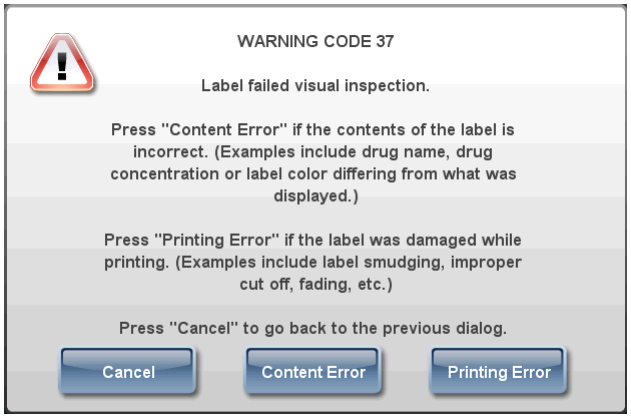
- Scan the label's barcode.
  - If the barcode is correct, the system plays an audible beep, briefly displays a confirmation message, and then displays the main screen.

- If the scanned barcode is incorrect, the system displays a message explaining the actions that can be taken.

WARNING **Incorrect syringe labels should be destroyed or disposed of to ensure that they are not used.**

CAUTION A failed label content confirmation is a serious issue. It means that the formulary is wrong. An SLS system administrator should be consulted immediately to review the logs and correct the formulary.

- If by visual inspection you can see that the label did not print correctly, press the **No** button. You are prompted to indicate whether there was a label content error or a problem printing the label.



After clicking either of the **Error** buttons, the system displays a message explaining the appropriate action to take.

WARNING **Incorrect syringe labels should be destroyed or disposed of to ensure that they are not used.**

WARNING If the barcode scan or you indicate that the label content was not correct or that the label was not printed correctly, contact the SLS system administrator or Codonics Technical Support (+1 440.243.1198) to resolve the problem before attempting to print a syringe label again.

CAUTION A failed label content confirmation is a serious issue. It means that the formulary is wrong. An SLS system administrator should be consulted immediately to review the logs and correct the formulary.

- If you are unable to scan the barcode, press the **Unable to Scan** button. You are prompted to discard the label and to try scanning the drug container barcode and printing the label again. Correct the scanning problem before attempting to print any more labels.

WARNING Unconfirmed syringe labels should be destroyed or disposed of to ensure that they are not used.

Custom Labels

In addition to printing syringe labels, the SLS can print custom labels that are configured for your site.

The next topic describes the custom label categories. For instructions about how to print custom labels, refer to “Printing Custom Labels” on page 4-23.

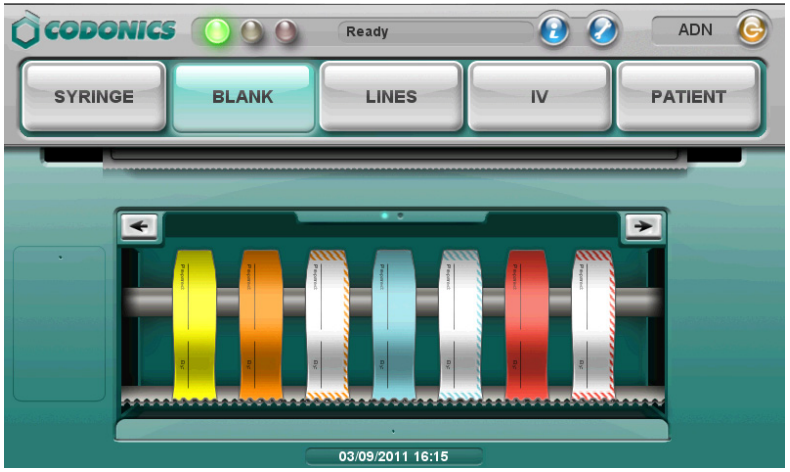
Custom Label Categories

By default, the system includes pre-defined categories for Blank, Lines, I.V., and Patient labels. These categories are described in the following topics.

NOTE: *Custom labels can be added using the SLS Administration Tool. For more information, refer to the SLS Administration Tool User's Manual.*

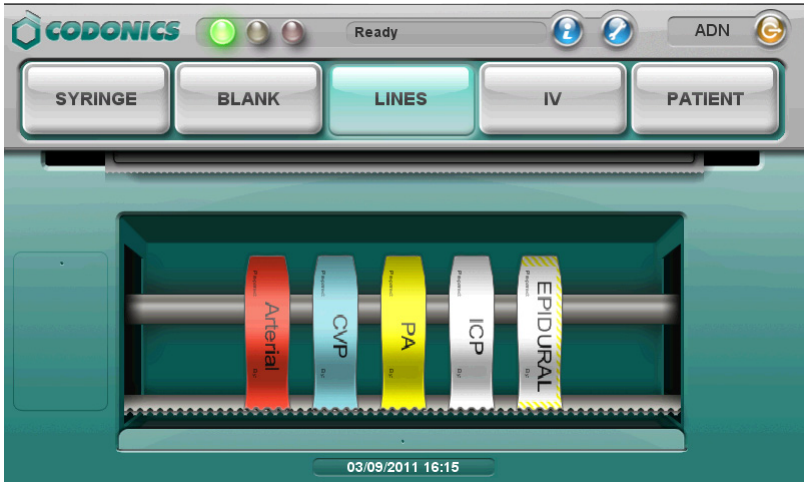
Blank

These blank syringe labels (no drug name or concentration) are provided for the labeling of drugs that do not have an NDC barcode on them, are not in the formulary, or cannot be read by the barcode scanner. One copy of the Blank label will be printed when it is selected.



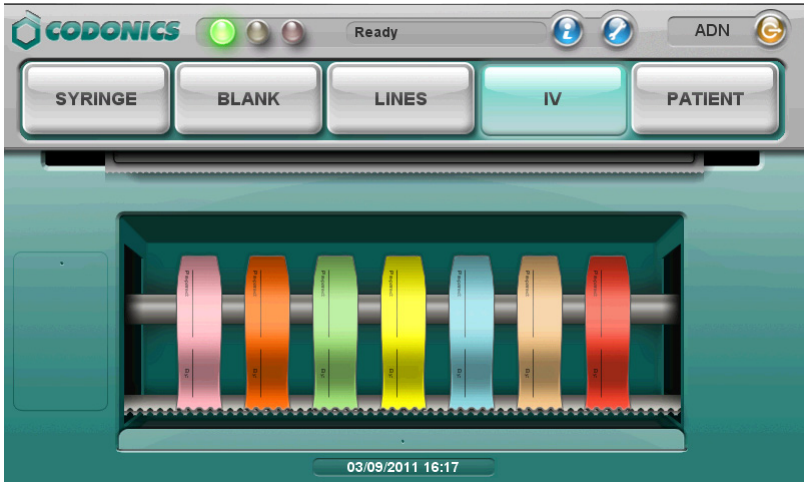
Lines

These labels are provided for the labeling of invasive monitoring lines used commonly in anesthesia. One copy of the Lines label will be printed when it is selected.



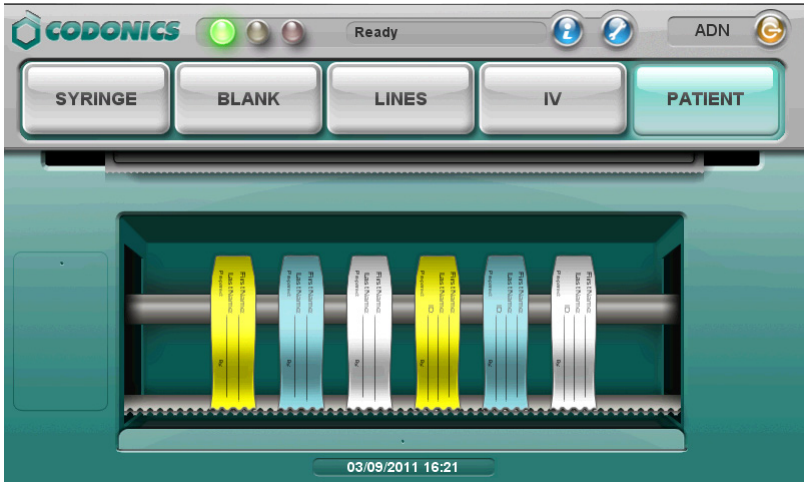
IV

These labels are provided for the labeling of the general IV line and catheter. Two copies of the IV label will be printed when it is selected.



Patient

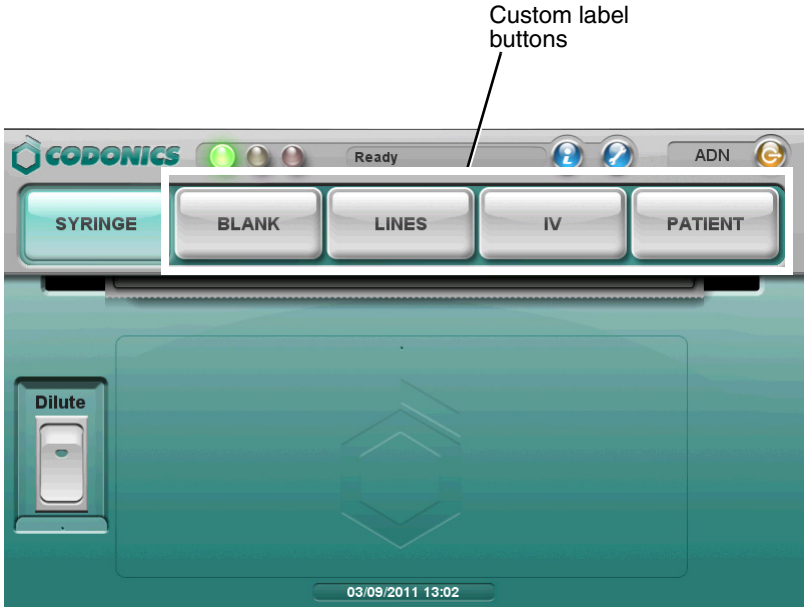
These labels are provided for the labeling of the reports and specimens. Two copies of the Patient label will be printed when it is selected.



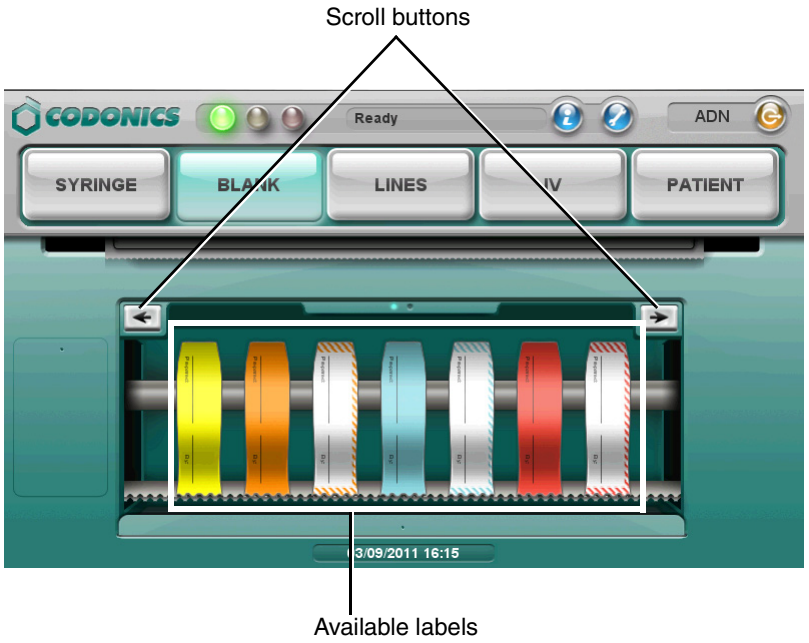
Printing Custom Labels

To print a custom label

1. Press one of the custom label buttons.



The system displays a selection of the custom labels that are available for that category.



2. If there are more custom labels than can be displayed at one time, click the left or right arrow buttons to scroll to the other labels.
3. Press the desired custom label to print it.

   The system prints the label. There is no pre-print or post-print confirmation of custom labels.

5 Maintenance

Ordering Supplies and Parts

The following table lists the label and print supplies that can be ordered from Codonics:

Supplies	Catalog Number
Ink cartridge	1SCT-LR833
Label media	1SCA-SLX33

The following table lists the replacement parts that can be ordered from Codonics:

Part	Catalog Number
Safe Label System external power supply	SLS-PS
Power cord, North America, Medical Grade	SP-00417
Power cord, Europe, Medical Grade	SP-00418

To order parts in the USA, contact Codonics Customer Service at:

Phone: **+1 440.243.1198**
Fax: **+1 440.243.1334**
Toll Free: **800.444.1198 (USA only)**
Web: **www.codonics.com** or **www.safelabel.com**

To order parts outside of the USA, contact your Codonics Customer Support Representative.

Cleaning the Enclosure

WARNING Always power off the system before cleaning. An electrical shock could occur if the system is powered on and liquid is spilled into it. Refer to "Powering Off the System" on page 3-20.

- To clean the system's enclosure, use a clean, lint-free cloth moistened with either warm water and mild soap, a diluted non-caustic detergent, or one of the following approved cleaning agents:
  - Ammonia: Dilution of Ammonia <3%
  - Alcohol: Ethanol 70%, Isopropanol 70%.
- Over time, ink overspray might gather at the base of the device. The device uses a vacuum system to gather most of this ink on a series of saturation pads. Eventually, these pads might need to be replaced. Contact Codonics Technical Support to determine if pad replacement is necessary.
- If ink has gotten onto the system's enclosure, it can be cleaned with an ammonia-based window cleaner and a lint-free cloth.
- If scanning barcodes is inconsistent or the device is having difficulty scanning, clean the scanner's glass window.

Cleaning Precautions

To avoid damage to the device, observe the following general precautions for cleaning the device:

- Apply the cleaner to a clean, lint-free cloth first and then clean the device. Liquid applied directly to the device could possibly leak inside the device and cause damage. Use extra caution when cleaning around the vents on the back of the touch screen and rear panel.
- Allow the device to completely dry before operating it again.
- Many plastic components are used in the SLS construction. Coat flecking and deformation is likely to occur if the device is wiped with chemical dusters, benzene, thinners, insecticides, or other solvents. Rubber and PVC materials left in contact with the SLS for extended periods of time will cause damage. Never use petroleum-based solutions or abrasive cleansers.
- Never use abrasive material.
- Always dilute cleaning agents according to the manufacturer's instructions, or use the lowest possible concentration.
- Do not allow the cleaning agent to remain on the device surfaces. Wipe it off immediately with a lint-free cloth moistened with water.

Disinfecting the Enclosure

It is recommended that you disinfect the product only when necessary as determined by your hospital's policy, to avoid long-term damage to the product.

The device must be cleaned first, as described in "Cleaning the Enclosure" on page 5-2, before using a general disinfecting agent.

Recommended disinfecting agents include:

- 1 part household bleach and 5 parts water solution
- A-456-N
- Virex II 256
- PDI Sani-Cloth®

WARNING Codonics makes no claims regarding the efficacy of the listed chemicals or methods as a means of controlling infection. Consult your hospital's infection control officer or epidemiologist.

Disinfecting Precautions

To avoid damage to the device, observe the following general precautions for disinfecting the device:

- Do not use Povodine, Sagrotan, or Mucocit disinfecting agents or strong solvents (for example, acetone).
- Do not use any disinfecting agents that corrode or damage polycarbonate.

Installing Update Packages or System Software

The SLS formulary, configuration, and system software can be updated.

A formulary update package includes the formulary database, which contains drug records and associated content such as drug-specific label templates, sound files, watermark images, and localization files. A configuration package includes the configuration settings for the SLS.

WARNING The formulary or configuration should be updated only when the SLS is not in use.

CAUTION Installing system software should only be performed as directed by Codonics Technical Support. Do not attempt to install system software without the assistance of Codonics Technical Support.

An administrator uses the SLS Administration Tool to create these update packages and store them on a USB flash drive for installation in an SLS. For more information about creating update packages, refer to the SLS Administration Tool User's Manual.

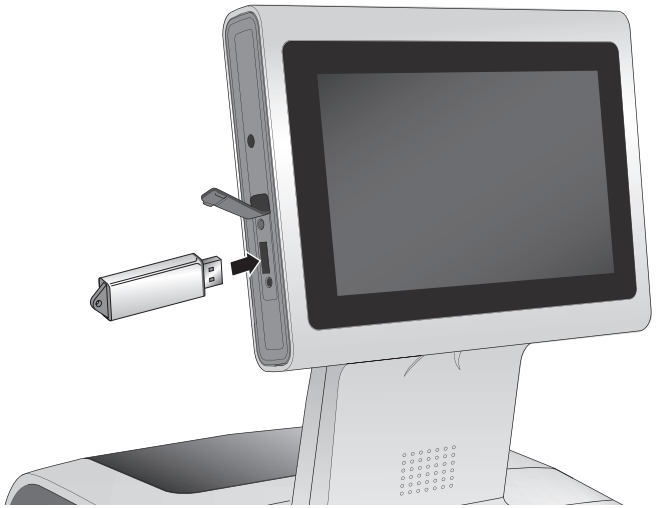
You might also need to update system software, which will be stored on a USB flash drive.

NOTE: *If the formulary update package contains a formulary in Test/Review mode, the yellow LED on the Dashboard will be on and a system message will indicate that the system is in Test/Review mode. Any syringe label that is printed while in this mode will have a watermark indicating that it is a test label and for demo use only.*

NOTE: *It is strongly recommended that each SLS customer create and set up a process and audit plan to check that the latest, approved versions of the formulary and configuration are correctly deployed on each SLS.*

To update packages or system software

1. Log in to the SLS, as described in “Logging In” on page 3-3.
2. Insert the USB flash drive into USB port1 on the left side of the touch screen.



Inserting the USB flash drive into the touch screen USB port 1

You are prompted to confirm installation of the packages or software on the USB flash drive.

3. Press the **Yes** button to continue with the installation.

   After copying the installation files to internal memory, the system displays a message indicating that the installation process is beginning and that the USB flash drive can be removed.

4. Remove the USB flash drive.

   The system displays status of the installation process. During installation, the system is not usable and cannot be interrupted.

When installation is complete, the system displays a completion message.

5. Press the **OK** button to dismiss the message.

The system then either restarts the software or restarts the entire system, depending on the specifics of the update. Formulary package updates do not require a full system restart. Configuration package updates require a full system restart. Software updates might require a full system restart, depending on the details of the software update.

CAUTION The SLS customer is responsible for ensuring that the correct formulary is being installed in the SLS.

CAUTION Practice standard information technology (IT) precautions to protect data associated with the formulary (for example, securing the content of the USB flash drive on which the formulary update package is stored).

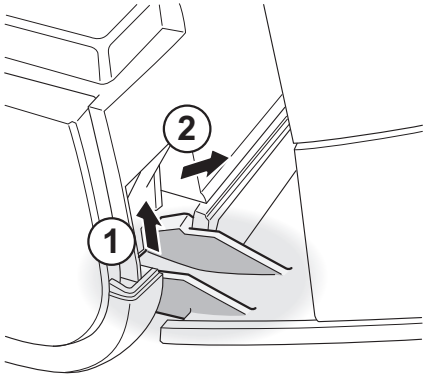
CAUTION The SLS customer is responsible for the accuracy of the data in the formulary, including drug data that has been copied from third-party sources such as drug databases.

Removing the Rear Cover

You might need to remove the rear cover for cleaning purposes, to clear a label jam, or to load labels in a restricted space.

To remove the rear cover

1. Partially open the rear cover (do not fully open the cover).
2. Hold the cover on both sides and gently lift it up until the hinges separate.
3. Carefully pull the cover away from the SLS.



Removing the rear cover

WARNING Re-glove in the event of a cut or pinch to prevent using a possible torn glove.

Calibrating the Touch Screen

The Calibrate Screen utility can be run when necessary to ensure that your finger will select the proper object on the touch screen.

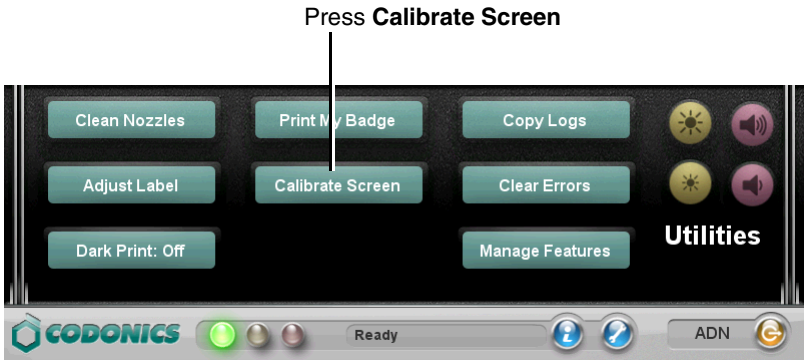
Run the Calibrate Screen utility if you notice that press points are out of alignment with the target object on the screen.

To calibrate the touch screen

1. Press the **Utilities** button at the top of the user interface.

The Utilities screen displays.

2. Press the **Calibrate Screen** button.



NOTE: *If pressing the button does not start the Calibrate Screen utility, the touch screen calibration might be very far off. Try pressing the area around the button until the button activates.*

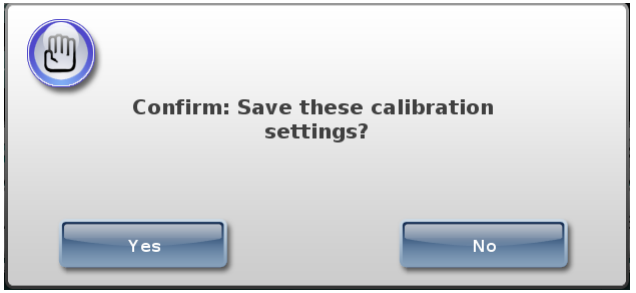
The system displays a message with instructions about how to perform the calibration.

3. Press the **OK** button to dismiss the message.

The Calibration screen displays.

4. Four targets will display sequentially on the Calibration screen. Carefully press the center of each target and hold your finger there until the next target displays.

   When the last target is calibrated, a calibration confirmation dialog box is displayed.



5. Press the **Yes** button to confirm the calibration.

   After confirming the calibration, the Utilities screen displays again.

   Press the **No** button to cancel this calibration and redisplay the Utilities screen.

Backing Up Log Files

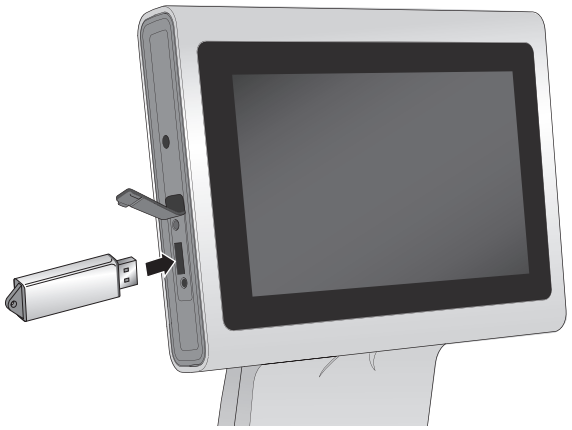
To prevent loss of the system logs stored on the SLS, it is strongly recommended that this data be backed up to another storage device on a regular basis. Also, if the SLS is experiencing problems, Codonics Technical Support might ask you to copy the system files to a USB flash drive and send them the drive.

Use the following procedure to copy the system files to a USB flash drive. You can then copy these files to another storage device for backup purposes.

CAUTION The system files copied to the USB flash drive are not encrypted.

To copy logs and other system files to a USB flash drive

1. Log in to the SLS, as described in “Logging In” on page 3-3.
2. Insert the USB flash drive into USB port 1 on the left side of the touch screen.

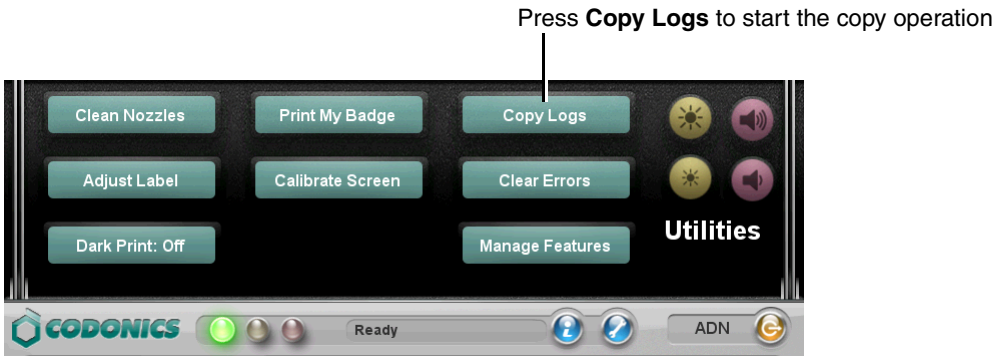


Inserting the USB flash drive into the touch screen USB port 1

3. Press the **Utilities** button at the top of the user interface.

The Utilities screen displays.

4. Press the **Copy Logs** button.



The system prompts you to confirm the copy operation.

5. Press the **Yes** button to continue.

   The system displays the progress of the copy operation.

6. When the copy operation is complete, press the **Utilities** button to close the Utilities screen.
7. Remove the USB flash drive.

Adding a Feature

Feature keys enable specific features of the SLS. Each feature key is associated with an integer value that identifies the name of the feature.

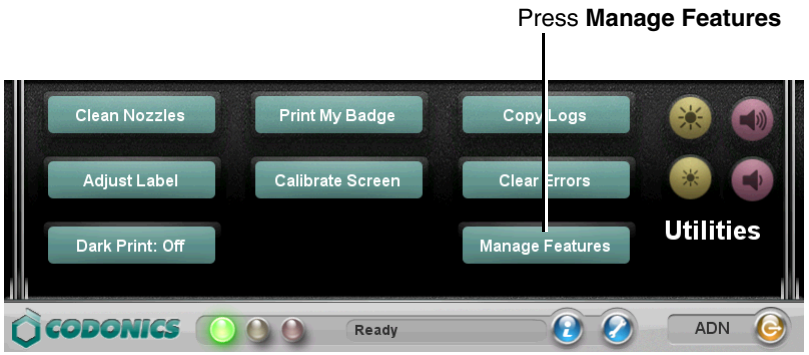
If you have purchased a new feature for SLS, Codonics will provide you with the feature key.

To add a feature

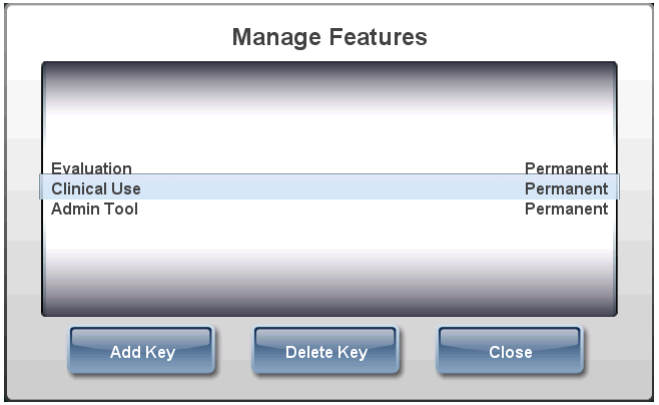
1. Press the **Utilities** button at the top of the user interface.

The Utilities screen displays.

2. Press the **Manage Features** button.

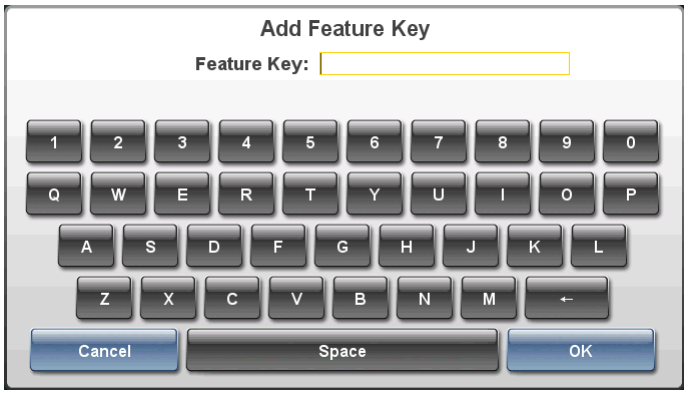


The **Manage Features** dialog box displays.



3. Press the **Add Key** button.

The **Add Feature Key** dialog box displays.



4. Enter the feature key, and then press the **OK** button to install the feature.

   You are prompted to confirm the feature installation.

Swapping Systems

You can move the SmartDrive from one SLS to another to move the system's configuration and formulary database, thus allowing the second SLS to operate exactly like the first. This feature is helpful when swapping an SLS for service purposes.

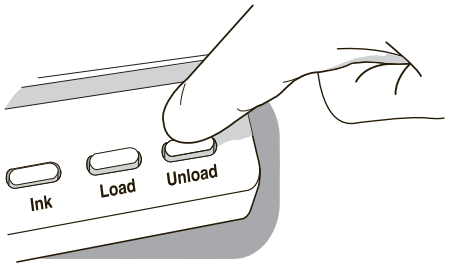
To swap systems, contact Codonics Technical Support so that they can direct you through the required steps.

Preparing the System for Shipping

If you have to ship the SLS for any reason (for example, to return it to Codonics for service), you must use the original boxes and packing materials. If you do not have the original box and packing materials, contact your Codonics representative for instructions on how to return the SLS.

To prepare the SLS for shipping

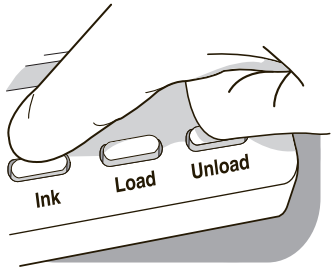
1. With the SLS powered on, open the front cover and press the Unload button to back out the label media so that it can be removed.



Unload button

2. Open the rear cover, remove the label media, and close the rear cover.
3. Shut down the SLS. Refer to "Shutting Down or Restarting the System" on page 3-19.

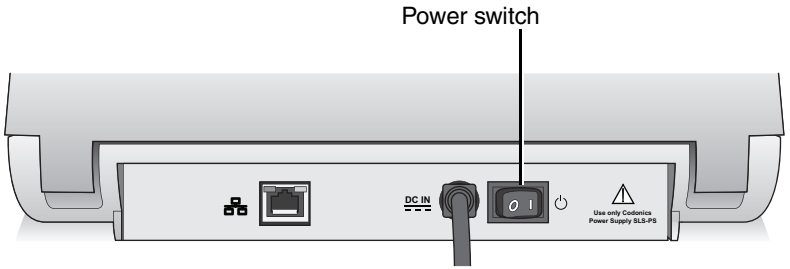
4. Press the Ink button.



Ink button

The ink cartridge carriage moves to a position that allows you access to the ink cartridge.

5. Remove the ink cartridge and close the front cover. For information about how to remove the ink cartridge, refer to “Installing the Ink Cartridge” on page 2-16.
6. Set the Power switch on the rear panel to Off.

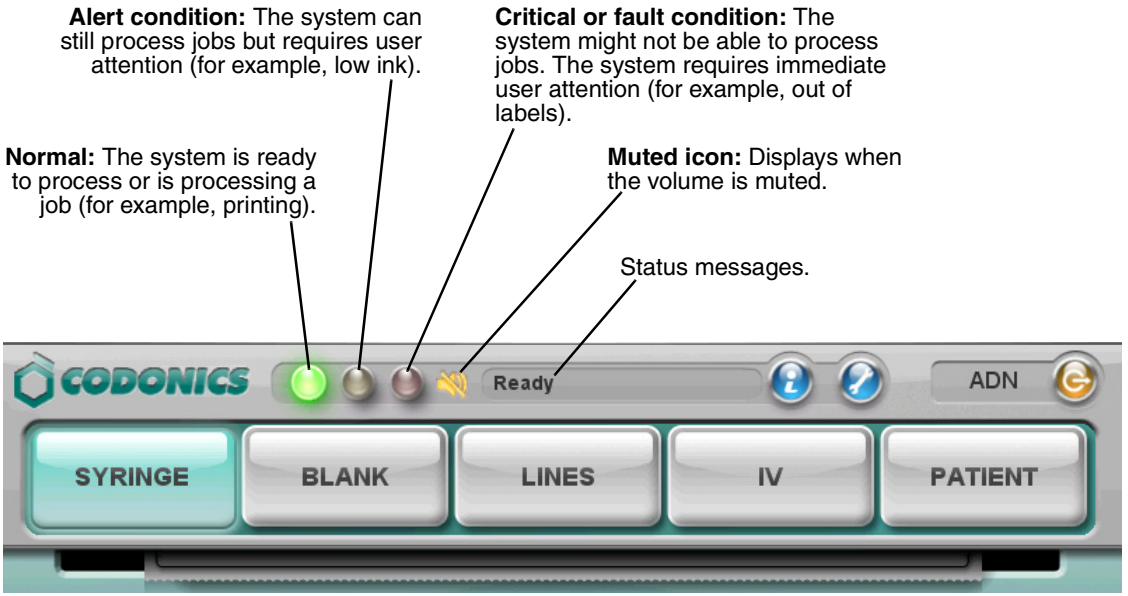


Power switch on the rear panel

6 Troubleshooting

Status Indicators

The Dashboard includes three LED-style lights that indicate the overall status of the SLS, a Muted icon if the volume has been turned off, and a status message area.

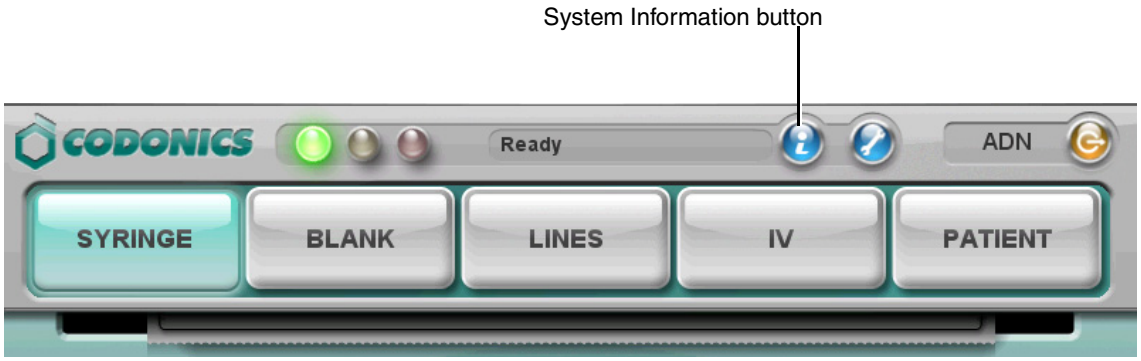


Displaying System Information

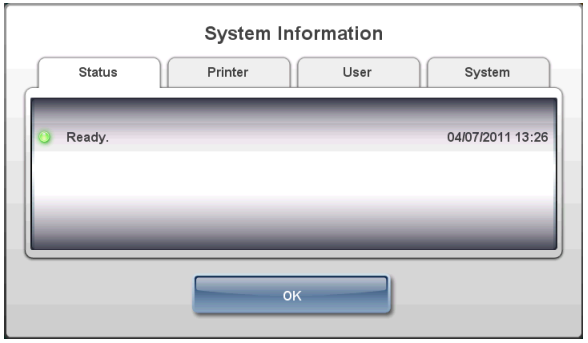
You can display information about the SLS configuration and its current status.

To display system information

Press the System Information button.



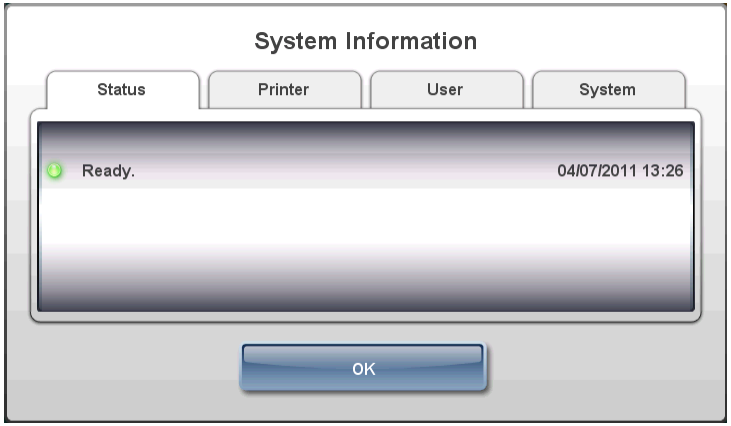
The System Information screen displays.



Press the **OK** button to dismiss the System Information screen.

The four tabs in the System Information screen include the information described in the following topics.

Status Tab



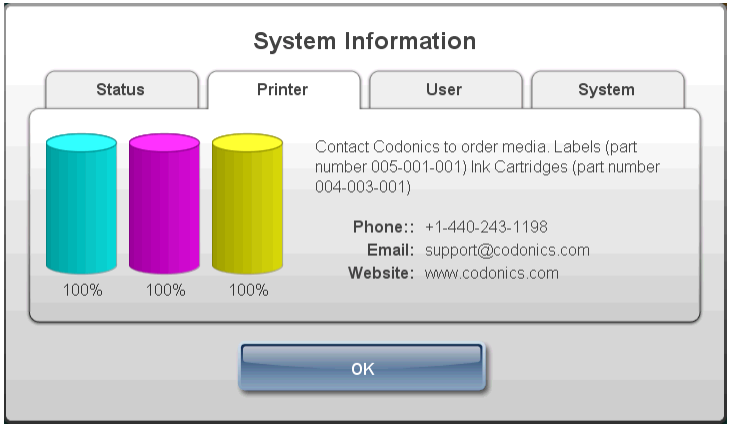
- A list of active system status messages:
  - Each line of the list has a descriptive message about the status
  - To the left of each message, there is an LED status indicator that displays the color-coded severity of the system state
  - To the right of each message, the time this status message first appeared is indicated

The LED status indicator severity states are:

- **Green:** Normal operation. No issues.
- **Yellow:** Alert condition. The system can still process jobs but requires user attention (for example, low ink).

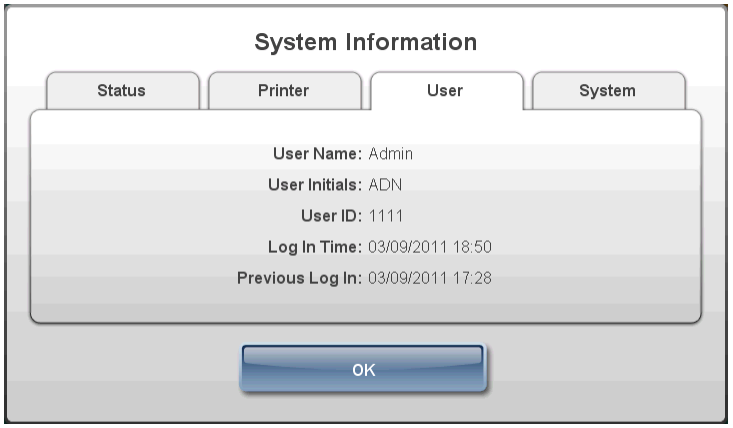
- **Red:** Critical or fault condition. The system might not be able to process jobs. The system requires immediate user attention (for example, out of labels).

Printer Tab



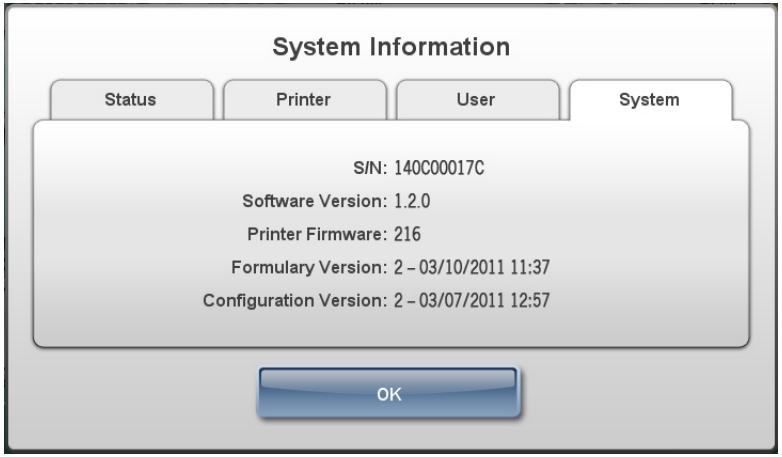
- Percent of ink remaining in the ink cartridge for all three colors
- Codonics part numbers for ordering ink cartridges and label media
- Codonics contact information for ordering ink cartridges and label media

User Tab



- Name of the currently logged-in user, along with their initials, ID, current login time, and previous login time

System Tab



- Serial number of the system
- Current software version
- Current printer firmware version
- Current formulary version
- Current configuration version

Troubleshooting Common Problems

The following table lists common problems, their possible causes, and how to solve them.

Table 6-1. Troubleshooting

Problem	Possible Causes	Solutions
System Problems:		
The system fails to power on.	The system does not have power connected.	Check the power cables. Check the power supply switch on the rear panel.
	The external power supply has failed.	Replace the external power supply.
The system has lost power.	The system does not have power connected.	Check the power cables. Check the power switch on the rear panel. Cycle power to the system.
	There is an internal power problem.	Contact Codonics Technical Support (+1 440.243.1198).
During startup, the system indicates that the SmartDrive is missing (error codes 70, 71).	The SmartDrive is not inserted in USB port 2 inside the touch screen rear panel door.	Insert the SmartDrive. Refer to “Inserting the SmartDrive” on page 2-13.
During startup, the system indicates that the SmartDrive is not compatible with the SLS application (error code 73).	The version number on the SmartDrive does not match the version number of the SLS application.	Contact Codonics Technical Support (+1 440.243.1198).
The system is not responding.	A variety of conditions.	Cycle power to the system.

Table 6-1. Troubleshooting (Continued)

Problem	Possible Causes	Solutions
The system starts in an error state.	A variety of software and/or hardware conditions.	Follow on-screen resolution prompts to correct issues. Refer to the on-screen information section about error codes. Contact Codonics Technical Support (+1 440.243.1198).
The user cannot log in.	The PIN has been forgotten or misplaced.	Create a new badge for the user with a new user ID.
The system indicates that it is in Test/Review mode.	The most recent formulary update package that was installed contains a formulary in Test/Review mode. This mode is used to test formularies before they are actually deployed on SLSs. The installed localization pack is in Test/Review mode and has not been validated yet by Codonics.	To return the SLS to the normal mode, a formulary update package at the Approved level must be installed. For more information about formulary levels, refer to the SLS Administration Tool User's Manual. Install a localization pack that has been validated by Codonics. For more information, refer to the SLS Localization Reference Guide and the SLS Administration Tool User's Manual.
The system indicates that a cover is open (error code 7).	The front or rear cover is open. While it is open, the printer cannot print labels.	Close the front or rear cover.
The system indicates that the printer is not responding (error code 8) or has an error (error codes 9, 12).	There is a problem with the label printer.	Cycle power to the system. If the problem persists, contact Codonics Technical Support (+1 440.243.1198).

Table 6-1. Troubleshooting (Continued)

Problem	Possible Causes	Solutions
The system indicates that disk space is low (error code 61).	Storage capacity is at or below 10%.	Contact Codonics Technical Support (+1 440.243.1198).
The system indicates that disk space is full (error code 62).	Storage capacity is below 1%.	Contact Codonics Technical Support (+1 440.243.1198).
The system indicates that the data on the SmartDrive is damaged (error code 72).	The SmartDrive is corrupted.	Contact Codonics Technical Support (+1 440.243.1198).
The system indicates that the SmartDrive is not valid (error code 74).	The SmartDrive does not have the necessary files.	Insert a valid SmartDrive and restart the system. If the problem persists with a SmartDrive that you believe to be valid, contact Codonics Technical Support (+1 440.243.1198).
Copying log files failed (error code 84).	The USB flash drive is full.	Delete files on the flash drive to provide enough storage space for the log files.
	The USB flash drive is damaged.	Try using another flash drive.
	The USB flash drive was removed while the copy operation was still being performed.	Insert the SmartDrive in USB port 2 inside the touch screen rear panel door and copy the log files again.
The system indicates that a system setting was not found (error code 85).	The installed version of the configuration is not compatible with the installed version of the SLS application.	Update the SLS application software or create a compatible version of the configuration update package and install that package. For more information, refer to the SLS Administration Tool User's Manual.

Table 6-1. Troubleshooting (Continued)

Problem	Possible Causes	Solutions
Touch Screen Problems:		
The touch screen does not respond properly when touched.	The touch screen is not properly calibrated.	Run the Calibrate Screen utility. Refer to "Calibrating the Touch Screen" on page 5-9.
The touch screen calibration failed (error code 19).	After running the Calibrate Screen utility, the user pressed the **No** button when prompted whether to save the calibration settings.	Run the Calibrate Screen utility again. Refer to "Calibrating the Touch Screen" on page 5-9.
	The user session timed out while the Calibrate Screen utility was running.	Log in and run the Calibrate Screen utility.
Formulary Problems:		
The formulary fails to load (error code 60).	The formulary database is corrupt.	Clear the error; refer to "Clearing Errors" on page 6-30. Create and load a new formulary update package. For information about how to create a formulary update package, refer to the SLS Administration Tool User's Manual.
The system indicates that the updated formulary is invalid (error code 81).	The formulary update package that was installed is damaged or the version of the formulary update package is not compatible with the current SLS software.	Create and load a new formulary update package. For information about how to create a formulary update package, refer to the SLS Administration Tool User's Manual. If the problem persists with a new formulary update package, contact Codonics Technical Support (+1 440.243.1198).

Table 6-1. Troubleshooting (Continued)

Problem	Possible Causes	Solutions
The system indicates that the formulary update is incomplete (error code 82).	The formulary update package did not install correctly.	Reinstall the formulary update package. If the problem occurs again, create and load a new formulary update package. For information about how to create a formulary update package, refer to the SLS Administration Tool User's Manual. If the problem persists when installing the new formulary update package, contact Codonics Technical Support (+1 440.243.1198).
Drug Container Barcode Verification Problems:		
A drug container failed verification when the barcode was scanned to print a syringe label (error code 20).	The user indicated that the drug in the formulary that matched the Container ID in the scanned drug container barcode is not the same drug as that in the drug container. To prevent a syringe being improperly labeled, that drug record is assigned a verification status of Failed and a label will not be printed anytime this drug container's barcode is scanned.	Make sure the barcode on the drug container is of good quality. Use the Administration Tool to correct the drug information in the Master Drug Database (MDD), create a new version of the formulary update package, and load the new version into the SLS. For more information, refer to the SLS Administration Tool User's Manual.

Table 6-1. Troubleshooting (Continued)

Problem	Possible Causes	Solutions
When a drug container's barcode is scanned to print a syringe label, the system indicates that the barcode previously failed drug verification (error code 21).	The first time this drug container barcode was scanned, the user indicated that the drug in the drug container did not match the drug found in the formulary with the same Container ID, To prevent a syringe being improperly labeled, the drug record's verification status was set to Failed and a label will not be printed anytime this drug container's barcode is scanned.	Make sure the barcode on the drug container is of good quality. Use the Administration Tool to correct the drug information in the MDD, create a new version of the formulary update package, and load the new version into the SLS. For more information, refer to the SLS Administration Tool User's Manual.
Printed Syringe Label Confirmation Problems:		
The displayed label in the pre-print confirmation screen was incorrect so the user pressed the **Cancel** button (error code 25).	There is an error in the formulary (unless the user just decided that they did not want to print the label).	If the label content or label color are incorrect, discard the label or the syringe (if the label is affixed to it), and contact your SLS system administrator.
The confirmation scan of a printed syringe label's barcode failed (error codes 30, 31, 32).	The barcode that was scanned was not a syringe barcode (error code 30).	Scan the barcode on the syringe label that was just printed.
	The barcode that was scanned was not the syringe barcode of the label that was just printed (error codes 31, 32).	Make sure that the label whose barcode you are scanning is the label that was just printed. • If it is not, then scan the correct label. • If it is, then the label did not print correctly. Do not use the label or the syringe (if the label is affixed to it). Contact your SLS system administrator and Codonics Technical Support (+1 440.243.1198) to notify them of the problem.

Table 6-1. Troubleshooting (Continued)

Problem	Possible Causes	Solutions
The visual confirmation of a printed syringe label failed [that is, on the post-printing confirmation dialog box, the user has pressed the **No** button (error code 37), and then pressed the **Content Error** (error code 35) or the **Printing Error** (error code 36) button].	The wrong drug information was printed on the syringe label (error code 35).	Discard the label or the syringe (if the label is affixed to it), try printing the syringe label again, and contact your SLS system administrator to notify them of the problem. If the wrong drug information is printed again, then the match between the Container ID in the scanned barcode and the Container ID in the drug record in the formulary is incorrect. The drug record in the formulary needs to be corrected. For more information, refer to the SLS Administration Tool User's Manual.
	The label print quality is not satisfactory (error code 36).	Discard the label or the syringe (if the label is affixed to it), try printing another one, and contact your SLS system administrator to notify them of the problem. If the problem continues, refer to the label problems and solutions described below in this table.
The confirmation of a printed syringe label is not able to be performed (error code 33).	The user pressed the **Unable to Scan** button.	Discard the label or the syringe (if the label is affixed to it). Print another label or a blank label. If the problem persists, contact your SLS system administrator.

Table 6-1. Troubleshooting (Continued)

Problem	Possible Causes	Solutions
Label Printing Problems:		
The test label fails to print (error code 1).	A variety of printer conditions.	Print the label again. Check to make sure that there are labels on the label media and that the label media is properly loaded. Check the ink cartridge. Cycle power to the system.
The test label did not print correctly (error code 2).	A variety of printer conditions.	Refer to the appropriate problem in this table for a solution.
The system indicates that the printing of a syringe label was cancelled.	The user cancelled the print operation at the pre-print confirmation.	If the content of the preview syringe label did not match the drug container whose barcode was scanned, contact your SLS system administrator to correct the drug record problem in the formulary.
The system indicates that it is out of label media (error code 6).	The label media is empty.	Install new label media. Refer to “Loading or Replacing the Label Media” on page 2-20.

Table 6-1. Troubleshooting (Continued)

Problem	Possible Causes	Solutions
Print is light, there is banding or gaps, or there is no printed image.	The ink cartridge is low or out of ink.	Replace the ink cartridge. Refer to "Installing the Ink Cartridge" on page 2-16.
	The ink cartridge is clogged.	Purge the ink cartridge (refer to "Cleaning the Ink Cartridge Nozzles" on page 6-23). Remove the ink cartridge and wipe the copper contacts with an alcohol-based wipe.
	The ink cartridge still has the protective seal on it.	Remove the ink cartridge and peel the protective seal from the cartridge.
	Low-quality labels are being used.	Use only Codonics labels. For ordering information, refer to "Ordering Supplies and Parts" on page 5-1.
	The ink cartridge has been refilled.	Use only new ink cartridges from Codonics.
Printed content is not properly centered on the label.	The media path is out of alignment.	Adjust the media path. Refer to "Adjusting the Media Path" on page 6-26.
Labels are incorrectly cut.	The cutter is out of adjustment.	Contact Codonics Technical Support (+1 440.243.1198).
	Labels are not being advanced correctly.	Reload the labels.
	The label offset is not set correctly.	Adjust the media path. Refer to "Adjusting the Media Path" on page 6-26.
Printed labels are not being cut.	The cutter is not properly positioned.	Contact Codonics Technical Support (+1 440.243.1198).

Table 6-1. Troubleshooting (Continued)

Problem	Possible Causes	Solutions
Labels are being printed but are not being dropped into the output bin.	Labels are jammed in the media path.	Clear the label jam. Refer to "Clearing a Label Media Jam" on page 6-21.
	A label is jammed in the discharge slot above the output bin.	Place your finger on the leading edge of the label and pull it forward to pull the label from the discharge slot.
Labels are not being printed correctly. For example, after scanning a barcode to confirm a printed label, the system displays an error message indicating that the scanned barcode is not correct.	The software, scanner, or printer is not operating properly.	Follow on-screen resolution prompts to correct issues.
Poor print quality.	Saturation.	Adjust the label black levels. Refer to "Adjusting the Label Black Levels" on page 6-28
	The wrong labels are loaded.	Load the correct labels for an SLS.
	The ink cartridge is not functioning properly.	Replace the ink cartridge with a proper SLS ink cartridge from Codonics. Refer to "Installing the Ink Cartridge" on page 2-16.
	The ink cartridge has been refilled.	Use only new ink cartridges from Codonics.
Ink Cartridge Problems:		
The system indicates that the ink cartridge is low (error code 5) on ink or out of ink (error code 4).	The ink cartridge is about to become empty or is empty.	Install a new ink cartridge. Refer to "Installing the Ink Cartridge" on page 2-16.

Table 6-1. Troubleshooting (Continued)

Problem	Possible Causes	Solutions
The system indicates that the ink cartridge is not installed (error code 3).	There is no ink cartridge in the carriage.	Install an ink cartridge. Refer to "Installing the Ink Cartridge" on page 2-16.
The ink cartridge carriage is not moving (error code 9).	An obstruction is preventing the ink cartridge carriage from moving.	Open the front cover and remove the obstruction. Press the Ink button to reset the position of the ink cartridge carriage.
Barcode Scanner Problems:		
The barcode scanner is not scanning.	The scanner's glass window is dirty.	Clean the scanner's glass window. Refer to "Cleaning the Enclosure" on page 5-2.
	The low-light red light is on, but the scanner laser cross-hairs are not on.	Shutdown the system from the touch screen and then cycle power to the system.
	The barcode symbology is not supported.	Contact Codonics Technical Support (+1 440.243.1198).
	The barcode on the printed syringe label has poor quality.	Follow the on-screen resolution prompt to fail the post-confirmation and try printing the label again. If the barcode quality is still poor, contact Codonics Technical Support (+1 440.243.1198).
	The barcode is incorrectly positioned.	Place the container or syringe below the scanner so that the red cross-hair lines up on the barcode. Placing the container or syringe closer to the cover, almost resting it on the cover, instead of placing it closer to the scanner, will also provide better results.

Table 6-1. Troubleshooting (Continued)

Problem	Possible Causes	Solutions
The system indicates that the scanner is not responding (error code 18).	There is a problem with the barcode scanner.	Cycle power to the system. If the problem persists, contact Codonics Technical Support (+1 440.243.1198).

Error Codes

The following table lists the error codes that could be displayed in system messages.

Table 6-2. Error Codes

Error Code	Description
01	The system detected an error while printing the test print.
02	The user indicated that the test print failed.
03	The ink cartridge is not installed.
04	The ink cartridge is out of ink.
05	The ink cartridge is low on ink.
06	There is no label media loaded.
07	The printer front or rear cover is open.
08	The printer is not responding to the system.
09	The ink cartridge carrier cannot move.
12	The printer is not responding to the system or has an error.
18	The scanner is not responding to the system.

Table 6-2. Error Codes (Continued)

Error Code	Description
19	The Calibrate Screen utility timed out before being completed, or the user has indicated that the touch screen calibration failed.
20	The user has indicated that the drug verification failed.
21	The scanned drug container barcode previously failed a drug verification.
25	On the syringe label pre-print confirmation dialog box, the user has pressed the **Cancel** button.
30	The scanned barcode is not a drug container barcode.
31	On the failed syringe label scan dialog box, the user has pressed the **Try Again** button.
32	On the failed syringe label scan dialog box, the user has pressed the **Cancel** button.
33	On the syringe label post-print confirmation dialog box, the user has pressed the **Unable to Scan** button.
35	On the syringe label failed visual confirmation dialog box, the user has pressed the **Content Error** button.
36	On the syringe label failed visual confirmation dialog box, the user has pressed the **Printing Error** button.
37	On the syringe label post-print confirmation dialog box, the user has pressed the **No** button.
60	The formulary database is corrupted or cannot be loaded.
61	The system disk space is low.
62	The system disk is full.

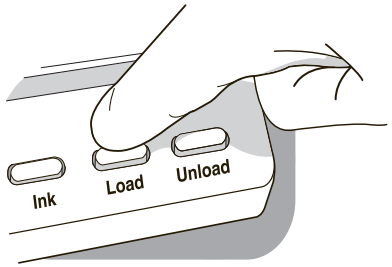
Table 6-2. Error Codes (Continued)

Error Code	Description
70	The SmartDrive has been removed from USB port 2, behind the touch screen rear panel door.
71	The SmartDrive is not inserted in USB port 2, behind the touch screen rear panel door.
72	The SmartDrive content is corrupt.
73	The version number on the SmartDrive does not match the version number of the SLS software.
74	The SmartDrive does not have the necessary files.
80	An unknown error was detected.
81	The formulary update package that was installed is damaged or the version of the formulary update package is not compatible with the current SLS software.
82	The formulary update package did not install correctly.
84	The USB flash drive that is inserted in USB port 1 on the side of the touch screen is either full, not valid, or has been removed in the middle of a log file copy operation.
85	The installed version of the configuration is not compatible with the installed version of the SLS software.

Clearing a Label Media Jam

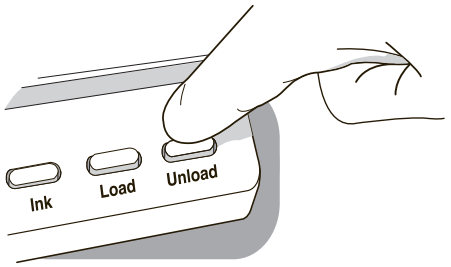
To clear a label media jam

1. Open the rear cover and tear the label media to separate the label roll from the portion of the label media that is jammed in the media path.
2. Open the front cover.
3. Gently remove the label media from under the front guide.
4. Press the Load button to advance any portion of the label media that is still in the media path. Remove the damaged labels.



Load button

5. Press the Unload button to reverse any portion of the label media that is still in the media path. Remove the damaged labels.



Unload button

6. If portions of the label media are still jammed in the media path, power off the system (refer to "Powering Off the System" on page 3-20). Then carefully remove the jammed portions of the label media with non-metallic tweezers. Do not try to pick the labels out with your fingers.

CAUTION If a label is peeled up in the media path, do not press the adhesive side of the label against the sheet metal guides.

WARNING Re-glove in the event of a cut or pinch to prevent using a possible torn glove.

Cleaning the Ink Cartridge Nozzles

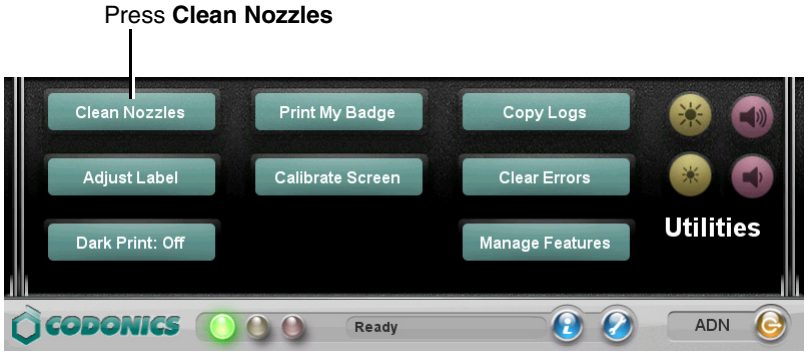
If label print quality is poor, you might need to clean the ink cartridge nozzles.

To clean the ink cartridge nozzles

1. Press the **Utilities** button at the top of the user interface.

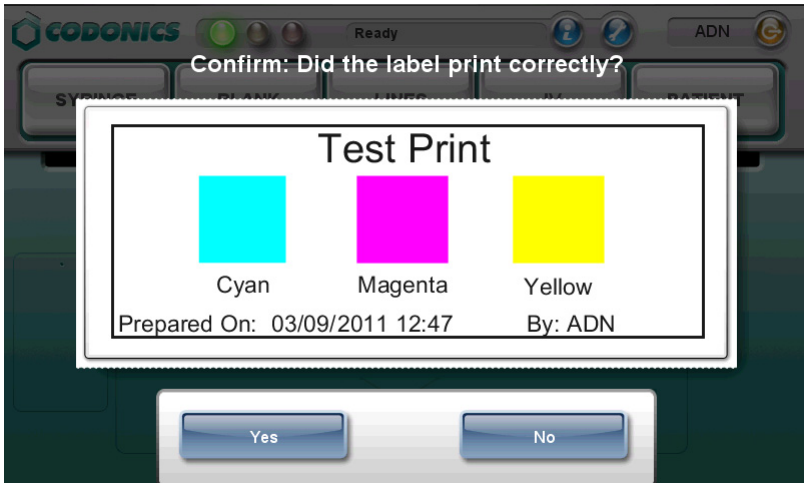
The Utilities screen displays.

2. Press the **Clean Nozzles** button.



The system cleans the ink cartridge nozzles, and then prints a test label.

You are then prompted to confirm that the test label printed correctly.

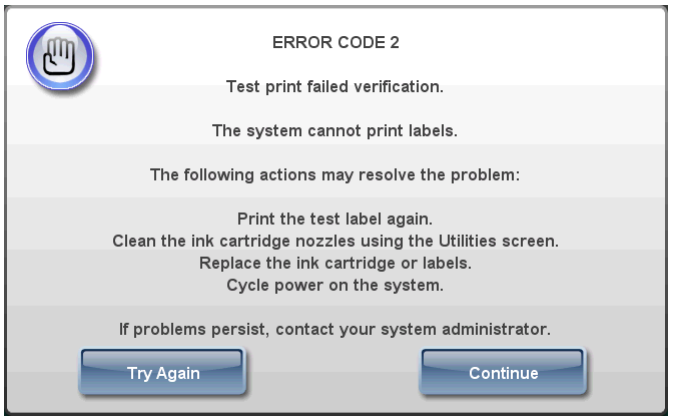


3. Review the following to ensure that the test label printed correctly:
   - The colors are correct
   - The label content is correctly centered
   - The print is not faded
   - There is no horizontal banding
   - The date and time are correct
   - The user's initials are correct
4. If the test label has printed correctly, press the **Yes** button.

   The main screen displays.

   If the test label prints incorrectly, press the **No** button.

A Test Print Failed Verification message displays.



5. To print another test label, press the **Try Again** button.

   Another test label prints and you are prompted again to confirm the test label.

   To attempt to resolve the printing problem, press the **Continue** button.

   The Utilities screen displays and the SLS is put into an out-of-service state.

6. To troubleshoot the printing problem and perform the recommended solution, refer to Table 6-1 on page 6-7.

   The system cannot leave the out-of-service state until you press the **Yes** button in response to the prompt to confirm that the test label printed correctly. So, after each solution you try, print another test label. If the utility you use does not do this automatically, you can log out and log in again to have the system print a test label.

7. If the test label still does not print correctly after trying the suggested solutions, contact your SLS system administrator.

Adjusting the Media Path

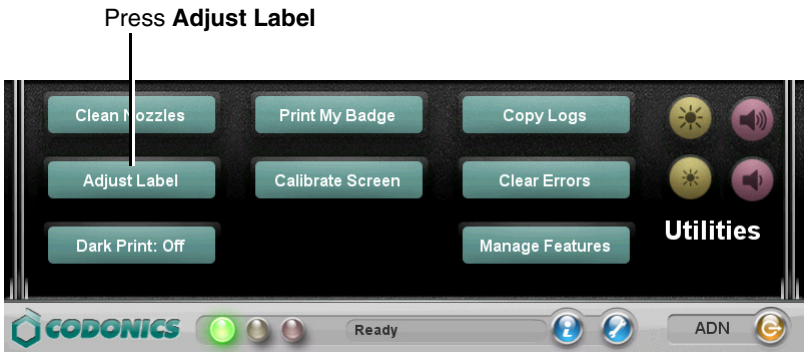
If the label is not properly centered on the printed labels or the labels are not being cut at the proper location on the media, you might need to adjust the media path.

To adjust the media path

1. Unload the label media, as described in “Clearing a Label Media Jam” on page 6-21.
2. Press the **Utilities** button at the top of the user interface.

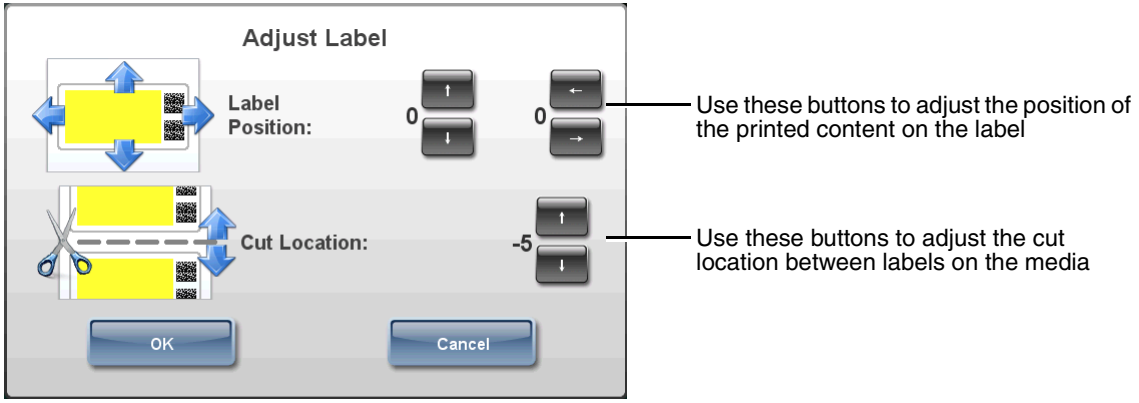
The Utilities screen displays.

3. Press the **Adjust Label** button.



The **Adjust Label** dialog box displays.

4. Use the adjustment buttons as described in the following figure.



For example, if the label content is correctly centered horizontally but is too low on the label vertically, use the up arrow button to move the print area up on the label.

5. After making the appropriate adjustments, press the **OK** button.
6. Close the Utilities screen.

7. Reload the label media, as described in "Loading or Replacing the Label Media" on page 2-20.
8. Print a custom label to see if the label prints correctly and use the Adjust Label utility again to make additional adjustments if needed.

Adjusting the Label Black Levels

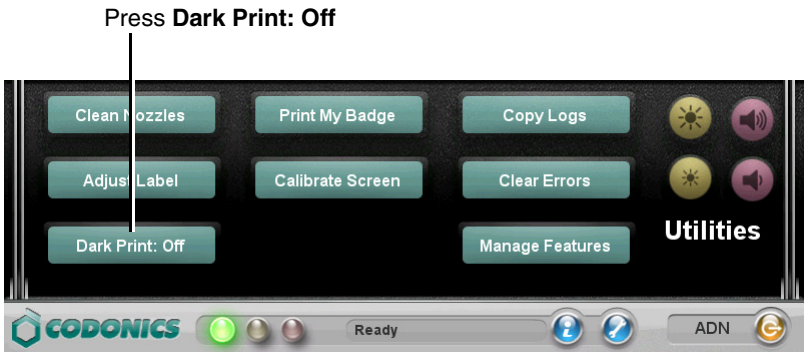
You can adjust the black levels of printed labels to improve their print contrast. If ink bleeding or barcode printing issues occur, the black levels adjustment should be turned off.

To adjust the label black levels

1. Press the **Utilities** button at the top of the user interface.

The Utilities screen displays.

2. Press the **Dark Print: Off** button (the button is in the **Dark Print: Off** state by default).



The button label changes to **Dark Print: On**, which indicates that the black levels adjustment has been turned on and the black levels for labels increased.

3. To turn off the black levels adjustment, press the **Dark Print: On** button.

Clearing Errors

Sometimes a permanent error state needs to be cleared in the SLS software.

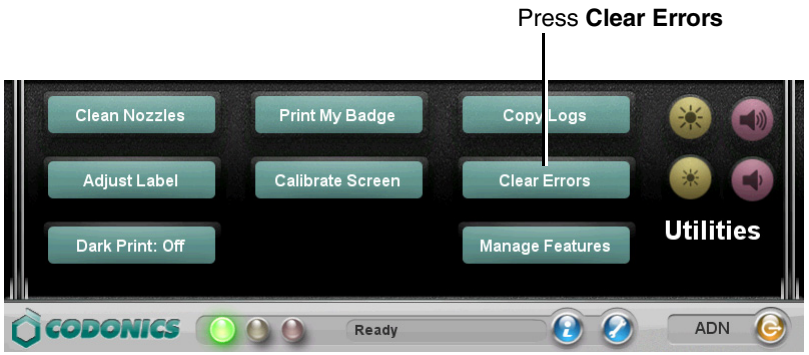
NOTE: *This function should only be performed by a qualified and trained SLS system administrator or in coordination with Codonics Technical Support.*

To clear errors

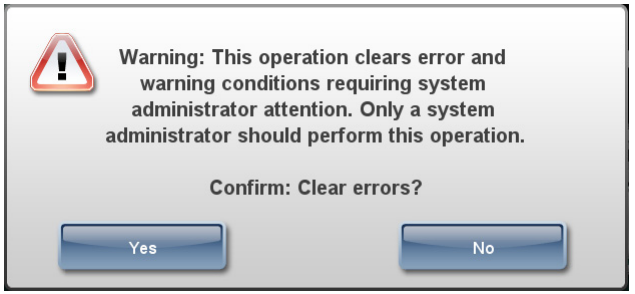
1. Press the **Utilities** button at the top of the user interface.

The Utilities screen displays.

2. Press the **Clear Errors** button.



A confirmation dialog box displays.



3. To continue with clearing the errors and restarting the system, press the **Yes** button. The SLS shuts down, restarts, and returns to the Login prompt.

A

Hazardous Material Information

Materials of Construction

Codonics has set very stringent standards for evaluating products to ensure the marketing of regulatory compliant products worldwide.

We do not intentionally add, nor are we aware, that the products or packaging contain the following materials:

- Mercury, except as used in lamp applications (for example, scanning lamps, backlit LCDs).
- Cadmium, except as used as thick film inks on printed circuit boards.
- Hexavalent Chromium, except as used as thick film inks on printed circuit boards, as chromate conversion coatings on metal surfaces, and as a photoresist on glass panels of cathode ray tubes.
- Polybrominated diphenyl ethers and polybrominated biphenyls.
- Bioavailable arsenic (small amounts of arsenic used in glass, LEDs, and semiconductors are not considered to be bioavailable).
- Bioavailable crystalline silica (small amounts of crystalline silica are used in certain paints, coatings, and filler materials).
- Polychlorinated biphenyls (PCBs).

- Asbestos.
- Organic tin (not used in tin lead solder applications).
- Ozone-depleting substances such as chlorofluorocarbons, methyl chloroform, and carbon tetrachloride.

Matériaux de Construction

Afin d'obtenir les certificats de conformité de ses produits dans le monde entier, Codonics utilise les standards d'évaluation les plus contraignants pour tester ses produits.

Codonics assure notamment n'avoir ajouté ou avoir été informé que soit ajouté les composants suivants dans son produit et son emballage:

- *Mercure, sauf dans le cas de systèmes d'éclairage (lampe à balayage, rétroéclairage LCD)*
- *Cadmium, à l'exception des encres de couche épaisse sur les circuits imprimés*
- *Chrome hexavalent, à l'exception des encres de couche épaisse sur les circuits imprimés, des protection de surface métallique et des photo résistances de tubes cathodiques*
- *Des éthers de diphényl polybromé ou des biphényls polybromés*
- *Arsenic (de très faible quantité d'arsénic sont présents dans le verre, les leds et les semi-conducteurs sans portée atteinte à l'organisme)*
- *Cristaux de silicium*
- *Biphenyls polychlorés*
- *Amiante*
- *Matières organiques*

- *Substances portant atteinte à la couche d'ozone tels que des carbones chlorofluorés du chloroforme et des tétrachlorures de carbone*

Manufacturing

During manufacturing operations that produce Codonics products (including packaging), no ozone depleting substances (such as chlorofluorocarbons, methyl chloroform, and carbon tetrachloride) are used.

Fabrication

Aucun composant susceptible de détruire la couche d'ozone ne sont utilisés lors de la fabrication (emballage inclus) des produits Codonics.

B

Specifications

Specifications (English)

System:	Integrated touch screen computer, 2D barcode scanner, color ink jet printer, audio feedback, and provision for a network interface	
Ink Cartridges:	One color cartridge (CMY)	
SmartDrive:	USB flash drive for storing configuration data, formulary database, log files	
Readable Barcodes:	GS1 DataBar Limited (RSS Limited), GS1 DataBar Stacked (RSS-14 Stacked), UPC-A, Data Matrix	
Writable Barcodes:	Data Matrix	
Dimensions:	Height: 16.5 in. (41.9 cm) Width: 10.43 in. (26.5 cm) Depth: 15.67 in. (39.8 cm)	
Weight:	14.5 lbs (6.6 kg)	
Power:	Universal Input: 100-240 VAC, 50/60 Hz	
Environmental:	*Operating:*	
	Temperature:	15–30°C (59–86°F)
	Humidity:	20%–80% noncondensing
	Shipping and Storage:	
	Altitude:	Sea Level to 5790 m
	Temperature (Hardware):	-22.2–51°C (-8–123.8°F)
	Temperature (Ink Cartridge and Label Media):	1–43°C (34–110°F)
	Humidity (Hardware):	5%–85% noncondensing
	Humidity (Ink Cartridge and Label Media):	5%–80% noncondensing

Medical Compliance and Regulatory:	FDA cleared to market per 510(k) K101439, Class II MDD CE, GMP/QSR, ISO13485: 2003, Safety IEC/EN 60601-1 and EMC/EMI EN 55011(A) & EN 60601-1-2 for Healthcare facilities
Classification:	Class 2 equipment, Product Code BSZ, Anesthesiology Device

CAUTION Federal law restricts this device to be sold for use by or on the order of a physician.

Specifications (French)

Système :	*Ordinateur avec écran tactile intégré, 2d bar code scanner, imprimante à jet d'encre, feed-back audio, et prestation d'un network interface*
Cartouches :	*Une cartouche coleur (CMY)*
Smart Drive :	*USB flash drive pour garder data du configuration, database de formulaire, dossiers du registre*
Bar codes livrable :	*RSS, UPC-A, B, C, Data Matrix*
Bar codes inscriptible :	*GS1 DataBar Limited (RSS Limited), GS1 DataBar Stacked (RSS-14 Stacked), UPC-A, Data Matrix*
Dimensions :	*Hauteur: 41.9 cm (16.5 in.)* *Largeur: 26.5 cm (10.43 in.)* *Profondeur: 39.8 cm (15.67 in.)*
Poids :	*14.5 lbs (6.6 kg)*
Puissance :	*Universel Input: 100-240 VAC, 50/60 Hz*

Conditions du travail :	Opération:	
	Température:	15–30°C (59–86°F)
	Humidité:	20%–80% non condensation
	Transport et Stockage:	
	Altitude:	Niveau de la mer to 5790 m
	Température (appareil):	-22.2–51°C (-8–123.8°F)
	Température (les cartouches et les et étiquettes):	1–43°C (34–110°F)
	Humidité (appareil):	5%–85% non condensation
	Humidité (les cartouches et les et étiquettes):	5%–80% non condensation
Conformité Médical/ Réglementaire :	*Conformité Médicale/Réglementaire: approuvé par la FDA, numéro 510(k) K101439, Class II MDD CE, GMP/QSR, ISO13485: 2003, Conformité IEC/EN 60601-1 et EMC/EMI-EN 55011 (A) & EN 60601-1-2 pour les établissements médicaux. Equipement de Classe 2, code de produit BSZ, appareil d'anesthésiologie.*	
Classification :	*Class 2 équipement, code de produit BSZ, appareil d'anesthésiologie*	

CAUTION Conformément à la loi, il est interdit de vendre cet appareil par l'ordre d'un médecin.

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